

EPA REGISTRATION NUMBER 71871-3 – VOL. 2

Material to be added to an e-Jacket/Jacket

Reg. No. 71871-3

1. ☒ Placement within the e-Jacket/jacket:
- ☐ Default: (chronological, top/newest)
 - ☐ Description: (PDF page number, i.e., "before page 45")
- _____
- _____

2. ☐ Send to Data Extraction contractors this material:

- ☐ Newly stamped accepted label
- ☒ Notification
- ☐ New CSF
- ☐ Other: _____

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: K Leavy

Phone: _____ Division: AI

Date: 10/20/10

DECISION PKG. NO. 440336SUBM. DUE DATE 10/22/10SUBMISSION BAR CODE # 882959REVIEWER KLCODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMEFILE SYMBOL/REG NO. 71871-3 PM 33 ACTION CODE 332 PRIADESCRIPTOR Notification FQPA NFQPA☐ CHILD RESISTANT PACKAGING: ☐ REQUIRED ☐ NOT REQUIREDREGISTRATION TYPE: ☐ CONDITIONAL ☐ UNCONDITIONAL ☐ RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

9/22/109/22/109/22/10

METHOD OF SUPPORT

FORMULATORS EXEMPTION

☐ CITE-ALL ☐ SELECTIVE
☐ NOT SUBMITTED ☐ N/A☐ SUBMITTED ☐ NOT SUBMITTED
☐ N/A

REVIEW(S) REQUESTED

DATA
PACK #DATE
SENTDUE
DATEDATE
RETURNEDCHEMISTRY ☐ ☐ ☐ ☐EFFICACY ☐ ☐ ☐ ☐ACUTE TOX. ☐ ☐ ☐ ☐RASSB TOX. ☐ ☐ ☐ ☐ENVIRON. FATE ☐ ☐ ☐ ☐FISH/WILDLIFE ☐ ☐ ☐ ☐OTHER: ☐ ☐ ☐ ☐

STATUS _____

RESPONSE CODE 1155RESPONSE DATE 10/20/10



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OCT 20 2010

Ms. Christina Swick
Regulatory Agent for,
Advanced Sterilization Products
33 Technology Drive
Irvine, CA 92618

Mail to: Lewis & Harrison
122 C street N. W., Suite 740
Washington, D.C. 20001

Subject: Sterrad Hydrogen Peroxide
EPA Registration Number 71871-3
Your Notification Dated September 22nd, 2010
EPA Received Date September 22nd, 2010

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, revise the Container Handling as per PR Notice 98-10, is acceptable.

The notification has been part of the permanent record of this file.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,

A handwritten signature in dark ink, appearing to read "M. Swindell", written over the printed name.

Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division(7510C)

LEWIS &
HARRISON

Consultants in Government Affairs

122 C Street, N.W., Suite 740
Washington, D.C. 20001
telephone 202.393.3903
fax 202.393.3906

September 22, 2010

HAND DELIVERED

Antimicrobials Division (Mail Code 7504P)
Office of Pesticide Programs
Document Processing Desk [NOTIFY]
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

ATTN: **Marshall Swindell**
Product Manager, Team 33

SUBJECT: **Advanced Sterilization Products**
STERRAD[®] Hydrogen Peroxide (EPA Reg. No. 71871-3)
Notification of Label Changes per PR Notice 98-10

Dear Mr. Swindell:

On behalf of Advanced Sterilization Products, we are notifying the Agency of changes to the *STERRAD[®] Hydrogen Peroxide* label in accordance with PR Notice 98-10. The purpose of this notification is to delete the disposal directions related to bottles since this product is only sold in cassettes.

Please find enclosed the following documents to support this notification:

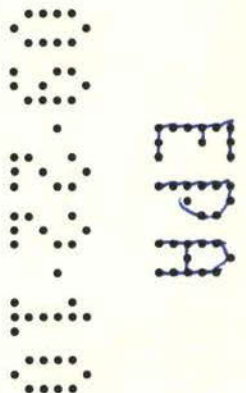
- 1) Pesticide Application Form;
- 2) One (1) copy of the proposed product label with the changes marked; and,
- 3) Three (3) copies of the proposed product label.

If you have any questions or comments, please contact me at 202-393-3903 ext. 16 or cswick@lewisharrison.com.

Sincerely,

Christina M. Swick

Christina M. Swick
Agent for Advanced Sterilization Products



**EPA**

United States
Environmental Protection Agency
 Washington, DC 20460

☐ **Registration**
☐ **Amendment**
☒ **Other NOTIFICATION**

OPP Identifier Number

Application for Pesticide – Section I

1. Company/Product Number 71871-3	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) STERRAD® Hydrogen Peroxide	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Advanced Sterilization Products 33 Technology Drive Irvine, CA 92618 <u>PLEASE SEND ALL CORRESPONDENCE TO</u> <u>"CONTACT POINT" LISTED BELOW</u> <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name: _____

Section – II

<input type="checkbox"/> Amendment – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification – Explain below.	<input type="checkbox"/> Other – Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)**Notification of in Accordance With PR Notice 98-10**

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 95-2 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be the subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Signature: Christina M. SwickDate: 9/22/10**THIS SUBMISSION IS NOT SUBJECT TO PRIA FEES****Section – III**

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
*Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	<input checked="" type="checkbox"/> Plastic	
		If "Yes" Package wgt.	No. per container	<input type="checkbox"/> Glass	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container Cassette		5. Location of Label Directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled					

Section – IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name Christina M. Swick, Lewis & Harrison 122 C Street, NW, Suite 740, Washington DC 20001	Title Agent	Telephone No. (Include Area Code) 202-393-3903 x16
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <u>Christina M. Swick</u>	3. Title Agent	
4. Typed Name Christina M. Swick, Lewis & Harrison, LLC	5. Date September 22, 2010	

STERRAD® HYDROGEN PEROXIDE AQUEOUS SOLUTION STERILANT

STERRAD® 100S™ Cassette	REF 10153
STERRAD® 50™ Cassette	REF 10154
STERRAD® 200™ Cassette	REF 10155
STERRAD® NX™ Cassette	REF 10156

FOR USE IN THE STERILIZATION OF
LABORATORY AND INDUSTRIAL EQUIPMENT

KEEP OUT OF REACH OF CHILDREN

DANGER

STATEMENT OF PRACTICAL TREATMENT

If In Eyes: Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

If On Skin or Clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes.

If Swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

If Inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment. You may also contact 1-877-208-6653 for emergency medical treatment information.

Note To Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

ACTIVE INGREDIENT: Hydrogen peroxide 59.0%
INERT INGREDIENTS: 41.0%
TOTAL: 100.0%

EPA Registration No.: 71871-3

EPA Establishment No.: 01871-CA-001

Net Contents of STERRAD® 100S Cassette:	Each cell contains NLT: 1750µL
Net Contents of STERRAD® 50 Cassette:	Each cell contains NLT: 1750µL
Net Contents of STERRAD® 200 Cassette:	Each cell contains NLT: 2246 mg
Net Contents of STERRAD® NX:	Each cell contains NLT: 1750µL



PRECAUTIONARY STATEMENTS

DANGER. CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Do not breathe vapor or spray mist. Wear protective eyewear (goggles, face shield or safety glasses) and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash clothing before reuse.

PHYSICAL AND CHEMICAL HAZARDS.

Hydrogen peroxide is a strong oxidizing agent and poses a hazard for fire, explosion or container rupture. Avoid contact with contamination or combustible materials. Do not use or store near heat or open flame. Shoes, clothing, or other combustible materials that have come into contact with hydrogen peroxide must be immediately and thoroughly rinsed with water to avoid potential fire hazards. In case of fire, use only water. Contain spills and dilute with 20 parts of water. After diluting the contained spill, use sodium metabisulfide or sodium sulfite (1.9 lbs. SO₂ equivalent per 500 mL of spilled material) may be used to deactivate the hydrogen peroxide.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to birds, mammals, fish and aquatic invertebrates. Do not charge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System and the permitting authority has been notified in writing prior to discharge. Do not discharge this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Manufactured by:

ASP ADVANCED STERILIZATION PRODUCTS®
a Johnson & Johnson company

Division of Ethicon, Inc.
33 Technology Drive, Irvine, CA 92618-9824
For Technical information call 1-888-783-7723

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102146-01

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

STERRAD® Hydrogen Peroxide is intended for sterilizing:

- Tissue culture equipment and materials
- Laboratory equipment (including glassware) and instrumentation
- Medical instruments and devices in veterinary facilities

STERRAD® Hydrogen Peroxide may be used for treating items made of aluminum, brass, Delrin, ethyl vinyl acetate (EVA), glass, Kraton, latex, neoprene, nylon, Monel, polycarbonate, polyethylene, polystyrene, polypropylene, polyurethane, polyvinyl chloride (PVC), silicone, stainless steel, Teflon/polytetrafluoroethylene (PTFE)

For Use In The STERRAD® 200 Sterilizer Only.

Two (2) Cycles/Cassette

- Each cell contains not less than 0.0868 oz. (0.898 ± 0.003 oz.) [2466 mg (2550 ± 84 mg)] of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
- If the yellow indicator has turned red, the cassette might have been damaged. Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise:
- Remove plastic wrap from cassette sleeve. Do not remove cassette from the remaining cardboard packaging.
- Orient the arrow so that it is on top of the cassette sleeve and pointing away from you.
- Insert the cassette sleeve into the STERRAD® 200 Sterilizer.
- Push the cassette sleeve completely into the injector. Once properly positioned, the cassette will automatically be accepted and positioned for use by the Sterilizer. The monitor will read "Cassette Accepted." If the cassette is not accepted because the barcode cannot be read or the cassette has expired, the monitor will read "Please Remove Cassette." Should this occur, please insert a new cassette.
- When the cassette is empty or has reached its labeled expiration date, or has been in the machine for 10 days (due to the higher temperature in the machine), it will automatically be re-inserted into the packaging and the monitor will display "Remove Cassette." Grasp and remove the sleeve containing the empty cassette. The chemical indicator on the cassette sleeve may have turned red due to the higher temperature in the machine.
- Discard the sleeves containing the empty cassettes as indicated in the disposal directions.
- If an UNUSED cassette extends or falls out of the sleeve, wear gloves to replace the cassette in the in the original sleeve and call ASP Customer Service.
- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® 200 Sterilizer cycle time is approximately 75 minutes.
- **Refer to STERRAD® 200 Sterilizer Operator's Guide for additional information.**

- OR -

For Use In The STERRAD® NX Sterilizer Only.

Five (5) Cycles/Cassette

- Each cell contains not less than 0.592 fl. oz. (0.609 ± 0.017 fl. oz.) [1750 µL (1800 µL ± 50 µL)] of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
- If the yellow indicator has turned red, the cassette might have been damaged. Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise:
- Remove plastic wrap
- Remove cassette from box
- Insert the cassette into the STERRAD® NX Sterilizer.
- The cassette will be accepted automatically
- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® NX Sterilizer has two cycle times: One is Standard cycle for 28 minutes and the other is Advanced cycle for 38 minutes
- **Refer to STERRAD® NX Sterilizer Operator's Guide for additional information.**



For Use In The STERRAD® 50 Sterilizer Only.

Five (5) Cycles/Cassette

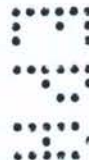
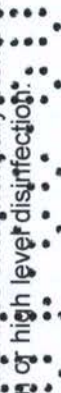
- Each cell contains not less than 0.592 fl. oz. (0.609 ± 0.017 fl. oz.) [(1750 µL (1800µL ± 50µL))] of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
- If the yellow indicator has turned red, the cassette might have been damaged. Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise:
- Remove plastic wrap from cassette sleeve. Do not remove cassette from the remaining cardboard packaging.
- Orient the arrow so that it is on top of the cassette sleeve and pointing away from you.
- Insert the cassette sleeve into the STERRAD® 50 Sterilizer.
- Push the cassette sleeve completely into the injector. Once properly positioned, the cassette will automatically be accepted and positioned for use by the Sterilizer. The monitor will read "Cassette Accepted." If the cassette is not accepted because the barcode cannot be read or the cassette has expired, the monitor will read "Please Remove Cassette." Should this occur, please insert a new cassette.
- When the cassette is empty or has reached its labeled expiration date, or has been in the machine for 10 days (due to the higher temperature in the machine), it will automatically be re-inserted into the packaging and the monitor will display "Remove Cassette." Grasp and remove the sleeve containing the empty cassette. The chemical indicator on the cassette sleeve may have turned red due to the higher temperature in the machine.
- Discard the sleeves containing the empty cassettes as indicated in the disposal directions.
- If an UNUSED cassette extends or falls out of the sleeve, wear gloves to replace the cassette in the original sleeve and call ASP Customer Service.
- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® 50 Sterilizer cycle time is approximately 45 minutes.
- **Refer to STERRAD® 50 Sterilizer Operator's Guide for additional information.**

For Use In The STERRAD® 100S Sterilizer Only.

Five (5) Cycles/Cassette

- Each cell contains not less than 0.592 fl. oz. (0.609 ± 0.017 fl. oz.) [(1750 µL (1800µL ± 50µL))] of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
- If the yellow indicator has turned red, the cassette might have been damaged. Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise:
- Remove plastic wrap
- Remove cassette from box.
- Insert the cassette sleeve into the STERRAD® 100S Sterilizer.
- The cassette will be accepted automatically.
- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® 100S Sterilizer cycle time is approximately 55 minutes.
- **Refer to STERRAD® 100S Sterilizer Operator's Manual for additional information.**

This product is not to be used as a terminal sterilant / high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization at high level disinfection.



STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: Keep product in its original packaging at a controlled room temperature, between 15° - 30°C (59° - 86°F). Do not expose product to direct sunlight, radiant heat, powdered metals, permanganates, cyanide, hexavalent chromium compounds, other oxidizers, reducers, combustible materials or flammable vapors.

PESTICIDE DISPOSAL: **Bottles:** If bottle contains less than 50 mL, empty contents into sink with running water according to local regulatory agency requirements or dispose as hazardous waste.

Bottles and Cassettes: Hydrogen peroxide is classified as a DOT oxidizer and a hazardous waste under US EPA hazardous waste regulation and it is a violation of Federal law to improperly dispose of pesticides. If these wastes cannot be disposed of by use or according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING DISPOSAL: **Cassettes:** Discard empty container per hospital policy.

Bottles: Triple-rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

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STERRAD® HYDROGEN PEROXIDE AQUEOUS SOLUTION STERILANT

STERRAD® 100S™ Cassette	REF 10153
STERRAD® 50™ Cassette	REF 10154
STERRAD® 200™ Cassette	REF 10155
STERRAD® NX™ Cassette	REF 10156

FOR USE IN THE STERILIZATION OF
LABORATORY AND INDUSTRIAL EQUIPMENT

KEEP OUT OF REACH OF CHILDREN

DANGER

STATEMENT OF PRACTICAL TREATMENT

If In Eyes: Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

If On Skin or Clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes.

If Swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

If Inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment. You may also contact 1-877- 208-6653 for emergency medical treatment information.

Note To Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

ACTIVE INGREDIENT: Hydrogen peroxide 59.0%
INERT INGREDIENTS: 41.0%
TOTAL: 100.0%

EPA Registration No.: 71871-3

EPA Establishment No.: 071871-CA-001

Net Contents of STERRAD® 100S Cassette: Each cell contains NLT: 1750µL
Net Contents of STERRAD® 50 Cassette: Each cell contains NLT: 1750µL
Net Contents of STERRAD® 200 Cassette: Each cell contains NLT: 2246 mg
Net Contents of STERRAD® NX: Each cell contains NLT: 1750µL

PRECAUTIONARY STATEMENTS

DANGER. CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Do not breathe vapor or spray mist. Wear protective eyewear (goggles, face shield or safety glasses) and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash clothing before reuse.

PHYSICAL AND CHEMICAL HAZARDS.

Hydrogen peroxide is a strong oxidizing agent and poses a hazard for fire, explosion or container rupture. Avoid contact with contamination or combustible materials. Do not use or store near heat or open flame. Shoes, clothing, or other combustible materials that have come into contact with hydrogen peroxide must be immediately and thoroughly rinsed with water to avoid potential fire hazards. In case of fire, use only water. Contain spills and dilute with 20 parts of water. After diluting the contained spill, use sodium metabisulfide or sodium sulfite (1.9 lbs. SO₂ equivalent per 500 mL of spilled material) may be used to deactivate the hydrogen peroxide.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to birds, mammals, fish and aquatic invertebrates. Do not charge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System and the permitting authority has been notified in writing prior to discharge. Do not discharge this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Manufactured by:

ASP ADVANCED STERILIZATION PRODUCTS®

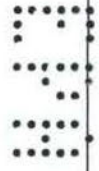
a Johnson & Johnson company

Division of Ethicon, Inc.
33 Technology Drive, Irvine, CA 92618-9824

For Technical information call 1-888-783-7723



102146-01



DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

STERRAD® Hydrogen Peroxide is intended for sterilizing:

- Tissue culture equipment and materials
- Laboratory equipment (including glassware) and instrumentation
- Medical instruments and devices in veterinary facilities

STERRAD® Hydrogen Peroxide may be used for treating items made of aluminum, brass, Delrin, ethyl vinyl acetate (EVA), glass, Kraton, latex, neoprene, nylon, Monel, polycarbonate, polyethylene, polystyrene, polypropylene, polyurethane, polyvinyl chloride (PVC), silicone, stainless steel, Teflon/polytetrafluoroethylene (PTFE)

For Use In The STERRAD® 200 Sterilizer Only.

Two (2) Cycles/Cassette

- Each cell contains not less than 0.0868 oz. (0.898 ± 0.003 oz.) [2466 mg (2550 ± 84 mg)] of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
- If the yellow indicator has turned red, the cassette might have been damaged. Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise:
- Remove plastic wrap from cassette sleeve. Do not remove cassette from the remaining cardboard packaging.
- Orient the arrow so that it is on top of the cassette sleeve and pointing away from you.
- Insert the cassette sleeve into the STERRAD® 200 Sterilizer.
- Push the cassette sleeve completely into the injector. Once properly positioned, the cassette will automatically be accepted and positioned for use by the Sterilizer. The monitor will read "Cassette Accepted." If the cassette is not accepted because the barcode cannot be read or the cassette has expired, the monitor will read "Please Remove Cassette." Should this occur, please insert a new cassette.
- When the cassette is empty or has reached its labeled expiration date, or has been in the machine for 10 days (due to the higher temperature in the machine), it will automatically be re-inserted into the packaging and the monitor will display "Remove Cassette." Grasp and remove the sleeve containing the empty cassette. The chemical indicator on the cassette sleeve may have turned red due to the higher temperature in the machine.
- Discard the sleeves containing the empty cassettes as indicated in the disposal directions.
- If an UNUSED cassette extends or falls out of the sleeve, wear gloves to replace the cassette in the original sleeve and call ASP Customer Service.
- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® 200 Sterilizer cycle time is approximately 75 minutes.
- **Refer to STERRAD® 200 Sterilizer Operator's Guide for additional information.**

- OR -

For Use In The STERRAD® NX Sterilizer Only.

Five (5) Cycles/Cassette

- Each cell contains not less than 0.592 fl. oz. (0.609 ± 0.017 fl. oz.) [1750 µL (1800 µL ± 50 µL)] of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
- If the yellow indicator has turned red, the cassette might have been damaged. Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise:
- Remove plastic wrap
- Remove cassette from box
- Insert the cassette into the STERRAD® NX Sterilizer.
- The cassette will be accepted automatically
- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® NX Sterilizer has two cycle times: One is Standard cycle for 28 minutes and the other is Advanced cycle for 38 minutes
- **Refer to STERRAD® NX Sterilizer Operator's Guide for additional information.**

For Use In The STERRAD® 50 Sterilizer Only.

Five (5) Cycles/Cassette

- Each cell contains not less than 0.592 fl. oz. (0.609 ± 0.017 fl. oz.) [(1750 µL (1800uL ± 50µL)] of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
- If the yellow indicator has turned red, the cassette might have been damaged. Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise:
- Remove plastic wrap from cassette sleeve. Do not remove cassette from the remaining cardboard packaging.
- Orient the arrow so that it is on top of the cassette sleeve and pointing away from you.
- Insert the cassette sleeve into the STERRAD® 50 Sterilizer.
- Push the cassette sleeve completely into the injector. Once properly positioned, the cassette will automatically be accepted and positioned for use by the Sterilizer. The monitor will read "Cassette Accepted." If the cassette is not accepted because the barcode cannot be read or the cassette has expired, the monitor will read "Please Remove Cassette." Should this occur, please insert a new cassette.
- When the cassette is empty or has reached its labeled expiration date, or has been in the machine for 10 days (due to the higher temperature in the machine), it will automatically be re-inserted into the packaging and the monitor will display "Remove Cassette." Grasp and remove the sleeve containing the empty cassette. The chemical indicator on the cassette sleeve may have turned red due to the higher temperature in the machine.
- Discard the sleeves containing the empty cassettes as indicated in the disposal directions.
- If an UNUSED cassette extends or falls out of the sleeve, wear gloves to replace the cassette in the original sleeve and call ASP Customer Service.
- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® 50 Sterilizer cycle time is approximately 45 minutes.
- **Refer to STERRAD® 50 Sterilizer Operator's Guide for additional information.**

For Use In The STERRAD® 100S Sterilizer Only.

Five (5) Cycles/Cassette

- Each cell contains not less than 0.592 fl. oz. (0.609 ± 0.017 fl. oz.) [(1750 µL (1800uL ± 50µL)] of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
- If the yellow indicator has turned red, the cassette might have been damaged. Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise:
- Remove plastic wrap
- Remove cassette from box.
- Insert the cassette sleeve into the STERRAD® 100S Sterilizer.
- The cassette will be accepted automatically.
- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® 100S Sterilizer cycle time is approximately 55 minutes.
- **Refer to STERRAD® 100S Sterilizer Operator's Manual for additional information.**

This product is not to be used as a terminal sterilant / high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: Keep product in its original packaging at a controlled room temperature, between 15° - 30°C (59° - 86°F). Do not expose product to direct sunlight, radiant heat, powdered metals, permanganates, cyanide, hexavalent chromium compounds, other oxidizers, reducers, combustible materials or flammable vapors.

PESTICIDE DISPOSAL: Hydrogen peroxide is classified as a DOT oxidizer and a hazardous waste under US EPA hazardous waste regulation and it is a violation of Federal law to improperly dispose of pesticides. If these wastes cannot be disposed of by use or according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING: Discard empty container per hospital policy.

102146-01

Material to be added to an e-Jacket/Jacket

Reg. No. 71871-3

1. ☒ Placement within the e-Jacket/jacket:

- ☐ Default: (chronological, top/newest)
 - ☐ Description: (PDF page number, i.e., "before page 45")
-
-

2. ☐ Send to Data Extraction contractors this material:

- ☐ Newly stamped accepted label
- ☐ Notification
- ☐ New CSF
- ☒ Other: Amendment

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: K Leavy

Phone: 308-6237 Division: AD

Date: 7/15/09

DECISION PKG. NO. 411373SUBM. DUE DATE 7/20/09SUBMISSION BAR CODE # 850335REVIEWER KL**CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS**FILE SYMBOL/REG NO. 71871-3 PM 33 ACTION CODE 302 **PRIA**DESCRIPTOR Amendment **FQPA** **NFQPA**☐ CHILD RESISTANT PACKAGING: ☐ REQUIRED ☐ NOT REQUIREDREGISTRATION TYPE: ☐ CONDITIONAL ☐ UNCONDITIONAL ☐ RESTRICTED USE

DATE ON APPLICATION

4, 20, 09

EPA RECEIVE DATE

4, 21, 09

PM RECEIVE DATE

4, 21, 09

METHOD OF SUPPORT

☐ CITE-ALL ☐ SELECTIVE
☐ NOT SUBMITTED ☐ N/A

FORMULATORS EXEMPTION

☐ SUBMITTED ☐ NOT SUBMITTED
☐ N/A

REVIEW(S) REQUESTED

DATA
PACK #DATE
SENTDUE
DATEDATE
RETURNEDCHEMISTRY ☐ ☐ ☐ ☐EFFICACY ☐ ☐ ☐ ☐ACUTE TOX. ☐ ☐ ☐ ☐RASSB TOX. ☐ ☐ ☐ ☐ENVIRON. FATE ☐ ☐ ☐ ☐FISH/WILDLIFE ☐ ☐ ☐ ☐OTHER: ☐ ☐ ☐ ☐

STATUS _____

RESPONSE CODE 1155RESPONSE DATE JUL 15 2009



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

JUL 15 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Mr. Robert Bennis
c/o Advance Sterilization Products
Lewis and Harrison
122 C Street NW
Suite 740
Washington, DC 20001

Subject: Sterrad Hydrogen Peroxide
EPA Registration Number 71871-3
Your Amendment Dated April 20th, 2009
EPA Received Date April 21st, 2009

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to delete the phrase, "Store upright at all times", change the expiration date from 8 days to 10 days, and to revise the "Directions for Use", is acceptable.

A stamped copy of the labeling is enclosed.

If you have questions concerning this letter, please contact Karen M. Leavy at (703)-308-6237.

Sincerely,

A handwritten signature in cursive script, appearing to read "M. Swindell".

Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobials Division(7510P)

STERRAD®
HYDROGEN PEROXIDE
AQUEOUS SOLUTION STERILANT

STERRAD® 100S™ Cassette	REF 10153
STERRAD® 50™ Cassette	REF 10154
STERRAD® 200™ Cassette	REF 10155
STERRAD® NX™ Cassette	REF 10156

FOR USE IN THE STERILIZATION OF
LABORATORY AND INDUSTRIAL EQUIPMENT

KEEP OUT OF REACH OF CHILDREN
DANGER
STATEMENT OF PRACTICAL TREATMENT

If In Eyes: Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

If On Skin or Clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes.

If Swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

If Inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment. You may also contact 1-877-208-6653 for emergency medical treatment information.

Note To Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

ACTIVE INGREDIENT: Hydrogen peroxide 59.0%
INERT INGREDIENTS: 41.0%
TOTAL: 100.0%

EPA Registration No.: 71871-3
EPA Establishment No.: 071871-CA-001

Net Contents of STERRAD® 100S Cassette: Each cell contains NLT: 1750µL
Net Contents of STERRAD® 50 Cassette: Each cell contains NLT: 1750µL
Net Contents of STERRAD® 200 Cassette: Each cell contains NLT: 2246 mg
Net Contents of STERRAD® NX: Each cell contains NLT: 1750µL

PRECAUTIONARY STATEMENTS

DANGER. CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Do not breathe vapor or spray mist. Wear protective eyewear, goggles, face shield or safety glasses) and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash clothing before reuse.

PHYSICAL AND CHEMICAL HAZARDS.

Hydrogen peroxide is a strong oxidizing agent and poses a hazard for fire, explosion or container rupture. Avoid contact with contamination or combustible materials. Do not use or store near heat or open flame. Shoes, clothing, or other combustible materials that have come into contact with hydrogen peroxide must be immediately and thoroughly rinsed with water to avoid potential fire hazards. In case of fire, use only water. Contain spills and dilute with 20 parts of water. After diluting the contained spill, use sodium metabisulfide or sodium sulfite (1.9 lbs. SO₂ equivalent per 500 mL of spilled material) may be used to deactivate the hydrogen peroxide.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to birds, mammals, fish and aquatic invertebrates. Do not charge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System and the permitting authority has been notified in writing prior to discharge. Do not discharge this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Manufactured by:

ASP **ADVANCED STERILIZATION PRODUCTS®**
with **COMMONS** Johnson-Johnson company
EPA Letter Data Technology Drive, Irvine, CA 92618-9824
Division of Ethicon, Inc.

JUL 15 2009 Technical information call 1-888-783-7723

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as ©ASP, 2009
10271871-3
Registered under EPA Reg. No. 71871-3

ACCEPTED
with COMMENTS
EPA Letter Dated:

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

STERRAD® Hydrogen Peroxide is intended for sterilizing:

- Tissue culture equipment and materials
- Laboratory equipment (including glassware) and instrumentation
- Medical instruments and devices in veterinary facilities

STERRAD® Hydrogen Peroxide may be used for treating items made of aluminum, brass, Delrin, ethyl vinyl acetate (EVA), glass, Kraton, latex, neoprene, nylon, Monel, polycarbonate, polyethylene, polystyrene, polypropylene, polyurethane, polyvinyl chloride (PVC), silicone, stainless steel, Teflon/polytetrafluoroethylene (PTFE)



JUL 15 2008
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 71871-3

For Use In The STERRAD® 200 Sterilizer Only.

Two (2) Cycles/Cassette

- Each cell contains not less than 0.0868 oz. (0.898 ± 0.003 oz.) [2466 mg (2550 ± 84 mg)] of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
- If the yellow indicator has turned red, the cassette might have been damaged. Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise:
- Remove plastic wrap from cassette sleeve. Do not remove cassette from the remaining cardboard packaging.
- Orient the arrow so that it is on top of the cassette sleeve and pointing away from you.
- Insert the cassette sleeve into the STERRAD® 200 Sterilizer.
- Push the cassette sleeve completely into the injector. Once properly positioned, the cassette will automatically be accepted and positioned for use by the Sterilizer. The monitor will read "Cassette Accepted." If the cassette is not accepted because the barcode cannot be read or the cassette has expired, the monitor will read "Please Remove Cassette." Should this occur, please insert a new cassette.
- When the cassette is empty or has reached its labeled expiration date, or has been in the machine for 10 days (due to the higher temperature in the machine), it will automatically be re-inserted into the packaging and the monitor will display "Remove Cassette." Grasp and remove the sleeve containing the empty cassette. The chemical indicator on the cassette sleeve may have turned red due to the higher temperature in the machine.
- Discard the sleeves containing the empty cassettes as indicated in the disposal directions.
- If an UNUSED cassette extends or falls out of the sleeve, wear gloves to replace the cassette in the original sleeve and call ASP Customer Service.
- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® 200 Sterilizer cycle time is approximately 75 minutes.
- Refer to STERRAD® 200 Sterilizer Operator's Guide for additional information.

- OR -

For Use In The STERRAD® NX Sterilizer Only.

Five (5) Cycles/Cassette

- Each cell contains not less than 0.592 fl. oz. (0.609 ± 0.017 fl. oz.) [1750 µL (1800 µL ± 50 µL)] of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
- If the yellow indicator has turned red, the cassette might have been damaged. Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise:
- Remove plastic wrap
- Remove cassette from box
- Insert the cassette into the STERRAD® NX Sterilizer.
- The cassette will be accepted automatically
- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® NX Sterilizer has two cycle times: One is Standard cycle for 28 minutes and the other is Advanced cycle for 38 minutes
- Refer to STERRAD® NX Sterilizer Operator's Guide for additional information.

- OR -

For Use In The STERRAD® 50 Sterilizer Only.

Five (5) Cycles/Cassette

- Each cell contains not less than 0.592 fl. oz. (0.609 ± 0.017 fl. oz.) [(1750 µL ± 50 µL)] of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
- If the yellow indicator has turned red, the cassette might have been damaged. Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise:
- Remove plastic wrap from cassette sleeve. Do not remove cassette from the remaining cardboard packaging.
- Orient the arrow so that it is on top of the cassette sleeve and pointing away from you.
- Insert the cassette sleeve into the STERRAD® 50 Sterilizer.
- Push the cassette sleeve completely into the injector. Once properly positioned, the cassette will automatically be accepted and positioned for use by the Sterilizer. The monitor will read "Cassette Accepted." If the cassette is not accepted because the barcode cannot be read or the cassette has expired, the monitor will read "Please Remove Cassette." Should this occur, please insert a new cassette.
- When the cassette is empty or has reached its labeled expiration date, or has been in the machine for 10 days (due to the higher temperature in the machine), it will automatically be re-inserted into the packaging and the monitor will display "Remove Cassette." Grasp and remove the sleeve containing the empty cassette. The chemical indicator on the cassette sleeve may have turned red due to the higher temperature in the machine.
- Discard the sleeves containing the empty cassettes as indicated in the disposal directions.
- If an UNUSED cassette extends or falls out of the sleeve, wear gloves to replace the cassette in the original sleeve and call ASP Customer Service.
- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® 50 Sterilizer cycle time is approximately 45 minutes.
- **Refer to STERRAD® 50 Sterilizer Operator's Guide for additional information.**

- OR -

For Use In The STERRAD® 100S Sterilizer Only.

Five (5) Cycles/Cassette

- Each cell contains not less than 0.592 fl. oz. (0.609 ± 0.017 fl. oz.) [(1750 µL ± 50 µL)] of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
- If the yellow indicator has turned red, the cassette might have been damaged. Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise:
- Remove plastic wrap
- Remove cassette from box.
- Insert the cassette sleeve into the STERRAD® 100S Sterilizer.
- The cassette will be accepted automatically.
- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® 100S Sterilizer cycle time is approximately 55 minutes.
- **Refer to STERRAD® 100S Sterilizer Operator's Manual for additional information.**

This product is not to be used as a terminal sterilant / high level disinfectant on any surface or instrument that is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-disinfect and decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

JUL 15 2009

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg No. 71871-3

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: Keep product in its original packaging at a controlled room temperature, between 15° - 30°C (59° - 86°F). Do not expose product to direct sunlight, radiant heat, powdered metals, permanganates, cyanide, hexavalent chromium compounds, other oxidizers, reducers, combustible materials or flammable vapors.

PESTICIDE DISPOSAL: Bottles: If bottle contains less than 50 ml, empty contents into sink with running water according to local regulatory agency requirements or dispose as hazardous waste.

Bottles and Cassettes: Hydrogen peroxide is classified as a DOT oxidizer and a hazardous waste under US EPA hazardous waste regulation and it is a violation of Federal law to improperly dispose of pesticides. If these wastes cannot be disposed of by use or according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Cassettes: Discard empty container per hospital policy.

Bottles: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

102146-01

ACCEPTED
with COMMENTS
EPA Letter Dated:

JUL 15 2009
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 71871-3

433
30.724

33

LEWIS & HARRISON

Consultants in Government Affairs

122 C Street, N.W., Suite 740
Washington, D.C. 20001

telephone 202.393.3903
fax 202.393.3906

April 20, 2009

U.S. Environmental Protection Agency
Document Processing Desk (7504P)
Room S-4900
1200 Pennsylvania Ave. NW
Washington, D.C. 20460-0001

ATTENTION: Marshall Swindell
Product Manager, Team 33

SUBJECT: Advance Sterilization Products
Sterrad Hydrogen Peroxide
(EPA Reg. No. 71871-3)
Label Amendment

Dear Mr. Marshall Swindell:

On behalf of **Advance Sterilization Products**, I am submitting a label amendment for their product, **Sterrad Hydrogen Peroxide (EPA Reg. No. 71871-3)**. Following are the labeling changes for the amendment:

- 1 The labeling "Store upright at all times" in the STORAGE section is being deleted because the product is a cassette and not a bottle. These cassettes are like video cassettes, which can be stored either way. There is no upright for such a product. These sealed cells are protected by sealed plastic (resin) cover. These plastic cover cassettes are wrapped in sleeve and sleeve has leak indicator, which changes the color if there is a hydrogen peroxide leak.
- 2 The claim "When the cassette is empty or has reached its labeled expiration date, or has been in the machine for 8 days" has been changed to 10 days. The reason for this change is that the cassette can be adequately used for a full 10 days. It was only limited to 8 days previously due to the limitations of the cassette software.
- 3 The specific instructions for use of the STERRAD® NX Sterilizer are actually the same as the STERRAD® 100S sterilizer. For some reason the instructions were

inadvertently shown as different on the accepted label. Therefore, the verbiage has been changed to duplicate the 100S system. The cycle times for the STERRAD® NX Sterilizer will remain the same however, to comply with the correct cycle times for the slightly different machinery.

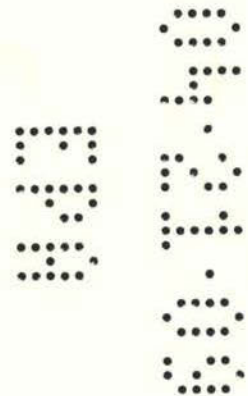
If you have any questions about the enclosed submission, please contact me by telephone at 202-393-3903 ext. 20 or by e-mail at bbrennis@lewisharrison.com.

Sincerely,



Robert S. Brennis
Agent for Advance Sterilization Products

Enclosure: Labels
 Application Form



**EPA**

United States
Environmental Protection Agency
Washington, DC 20460

- ☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 71871-3	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Advance Sterilization Products/ Sterrad Hydrogent Peroxide	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Envirox LLC 1938 E. Fairchild Street Danville, IL 61832 <u>PLEASE SEND ALL CORRESPONDENCE TO</u> <u>"CONTACT POINT" LISTED BELOW</u> <input checked="" type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

- ☐ Amendment - Explain below. ☐ Final printed labels in response to Agency letter dated _____
☐ Resubmission in response to Agency letter dated _____ ☐ "Me Too" Application
☒ Notification - Explain below. ☐ Other - Explain below

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This is an amendment to make some simple changes to accepted label. Please see the cover letter for explanations. The previously accepted Notification with typographical corrects has been reflected in this amendment.

Section - III**1. Material This Product Will Be Packaged In:**

Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other
If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt. No. per container	

***Certification must be submitted**

6. Manner in Which Label is Affixed to Product

- ☐ Lithograph
☐ Paper glued
☐ Stenciled

☐ Other _____**Section - IV****1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)**

Name: Robert S. Brennis, Lewis & Harrison 122 C St. NW, Suite 740, Washington, DC 20001	Title Agent for Advance Sterilization Products	Telephone No. (Include Area Code) 202-393-3903 ext 20
--	---	--

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete.
I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature

3. Title

Agent for Advance Sterilization Products

4. Typed Name

Robert S. Brennis

5. Date

April 20, 2009

6. Date Application Received

(Stamped)

STERRAD®
HYDROGEN PEROXIDE
AQUEOUS SOLUTION STERILANT

STERRAD® 100S™ Cassette	REF 10153
STERRAD® 50™ Cassette	REF 10154
STERRAD® 200™ Cassette	REF 10155
STERRAD® NX™ Cassette	REF 10156

FOR USE IN THE STERILIZATION OF
LABORATORY AND INDUSTRIAL EQUIPMENT

KEEP OUT OF REACH OF CHILDREN
DANGER
STATEMENT OF PRACTICAL TREATMENT

If In Eyes: Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

If On Skin or Clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes.

If Swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor.

If Inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment. You may also contact 1-877-208-6653 for emergency medical treatment information.

Note To Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

ACTIVE INGREDIENT: Hydrogen peroxide 59.0%
INERT INGREDIENTS: 41.0%
TOTAL: 100.0%

EPA Registration No.: 71871-3
EPA Establishment No.: 071871-CA-001

Net Contents of STERRAD® 100S Cassette: Each cell contains NLT: 1750µL
Net Contents of STERRAD® 50 Cassette: Each cell contains NLT: 1750µL
Net Contents of STERRAD® 200 Cassette: Each cell contains NLT: 2246 mg
Net Contents of STERRAD® NX: Each cell contains NLT: 1750µL

PRECAUTIONARY STATEMENTS

DANGER. CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Do not breathe vapor or spray mist. Wear protective eyewear (goggles, face shield or safety glasses) and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash clothing before reuse.

PHYSICAL AND CHEMICAL HAZARDS.

Hydrogen peroxide is a strong oxidizing agent and poses a hazard for fire, explosion or container rupture. Avoid contact with contamination or combustible materials. Do not use or store near heat or open flame. Shoes, clothing, or other combustible materials that have come into contact with hydrogen peroxide must be immediately and thoroughly rinsed with water to avoid potential fire hazards. In case of fire, use only water. Contain spills and dilute with 20 parts of water. After diluting the contained spill, use sodium metabisulfite or sodium sulfite (1.9 lbs. SO₂ equivalent per 500 mL of spilled material) may be used to deactivate the hydrogen peroxide.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to birds, mammals, fish and aquatic invertebrates. Do not charge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System and the permitting authority has been notified in writing prior to discharge. Do not discharge this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Manufactured by:

ASP **ADVANCED STERILIZATION PRODUCTS®**
a Johnson-Johnson company
Division of Ethicon, Inc.

33 Technology Drive, Irvine, CA 92618-9824

For Technical information call 1-888-783-7723

©ASP, 2009

102146-01

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

STERRAD® Hydrogen Peroxide is intended for sterilizing:

- Tissue culture equipment and materials
- Laboratory equipment (including glassware) and instrumentation
- Medical instruments and devices in veterinary facilities

STERRAD® Hydrogen Peroxide may be used for treating items made of aluminum, brass, Delrin, ethyl vinyl acetate (EVA), glass, Kraton, latex, neoprene, nylon, Monel, polycarbonate, polyethylene, polystyrene, polypropylene, polyurethane, polyvinyl chloride (PVC), silicone, stainless steel, Teflon/polytetrafluoroethylene (PTFE).

For Use In The STERRAD® 200 Sterilizer Only.

Two (2) Cycles/Cassette

- Each cell contains not less than 0.0868 oz. (0.898 ± 0.003 oz.) [2466 mg (2550 ± 84 mg)] of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
- If the yellow indicator has turned red, the cassette might have been damaged. Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise:
- Remove plastic wrap from cassette sleeve. Do not remove cassette from the remaining cardboard packaging.
- Orient the arrow so that it is on top of the cassette sleeve and pointing away from you.
- Insert the cassette sleeve into the STERRAD® 200 Sterilizer.
- Push the cassette sleeve completely into the injector. Once properly positioned, the cassette will automatically be accepted and positioned for use by the Sterilizer. The monitor will read "Cassette Accepted." If the cassette is not accepted because the barcode cannot be read or the cassette has expired, the monitor will read "Please Remove Cassette." Should this occur, please insert a new cassette.
- When the cassette is empty or has reached its labeled expiration date, or has been in the machine for 10 days (due to the higher temperature in the machine), it will automatically be re-inserted into the packaging and the monitor will display "Remove Cassette." Grasp and remove the sleeve containing the empty cassette. The chemical indicator on the cassette sleeve may have turned red due to the higher temperature in the machine.
- Discard the sleeves containing the empty cassettes as indicated in the disposal directions.
- If an UNUSED cassette extends or falls out of the sleeve, wear gloves to replace the cassette in the original sleeve and call ASP Customer Service.
- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® 200 Sterilizer cycle time is approximately 75 minutes.
- Refer to STERRAD® 200 Sterilizer Operator's Guide for additional information.

- OR -

For Use In The STERRAD® NX Sterilizer Only.

Five (5) Cycles/Cassette

- Each cell contains not less than 0.592 fl. oz. (0.609 ± 0.017 fl. oz.) [1750 µL (1800 µL ± 50 µL)] of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
 - If the yellow indicator has turned red, the cassette might have been damaged. Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise:
 - Remove plastic wrap ...
 - Remove cassette from box
 - Insert the cassette into the STERRAD® NX Sterilizer.
 - The cassette will be accepted automatically
- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® NX Sterilizer has two cycle times: One is Standard cycle for 28 minutes and the other is Advanced cycle for 38 minutes
- Refer to STERRAD® NX Sterilizer Operator's Guide for additional information.

For Use In The STERRAD® 50 Sterilizer Only.

Five (5) Cycles/Cassette

- Each cell contains not less than 0.592 fl. oz. (0.609 ± 0.017 fl. oz.) [(1750 ± 50 µL)] of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
- If the yellow indicator has turned red, the cassette might have been damaged. Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise:
- Remove plastic wrap from cassette sleeve. Do not remove cassette from the remaining cardboard packaging.
- Orient the arrow so that it is on top of the cassette sleeve and pointing away from you.
- Insert the cassette sleeve into the STERRAD® 50 Sterilizer.
- Push the cassette sleeve completely into the injector. Once properly positioned, the cassette will automatically be accepted and positioned for use by the Sterilizer. The monitor will read "Cassette Accepted." If the cassette is not accepted because the barcode cannot be read or the cassette has expired, the monitor will read "Please Remove Cassette." Should this occur, please insert a new cassette.
- When the cassette is empty or has reached its labeled expiration date, or has been in the machine for 10 days (due to the higher temperature in the machine), it will automatically be re-inserted into the packaging and the monitor will display "Remove Cassette." Grasp and remove the sleeve containing the empty cassette. The chemical indicator on the cassette sleeve may have turned red due to the higher temperature in the machine.
- Discard the sleeves containing the empty cassettes as indicated in the disposal directions.
- If an UNUSED cassette extends or falls out of the sleeve, wear gloves to replace the cassette in the original sleeve and call ASP Customer Service.
- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® 50 Sterilizer cycle time is approximately 45 minutes.
- **Refer to STERRAD® 50 Sterilizer Operator's Guide for additional information.**

For Use In The STERRAD® 100S Sterilizer Only.

Five (5) Cycles/Cassette

- Each cell contains not less than 0.592 fl. oz. (0.609 ± 0.017 fl. oz.) [(1750 ± 50 µL)] of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
- If the yellow indicator has turned red, the cassette might have been damaged. Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise:
- Remove plastic wrap
- Remove cassette from box.
- Insert the cassette sleeve into the STERRAD® 100S Sterilizer.
- The cassette will be accepted automatically.
- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® 100S Sterilizer cycle time is approximately 55 minutes.
- **Refer to STERRAD® 100S Sterilizer Operator's Manual for additional information.**

This product is not to be used as a terminal sterilant / high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: Keep product in its original packaging at a controlled room temperature, between 15° - 30°C (59° - 86°F). Do not expose product to direct sunlight, radiant heat, powdered metals, permanganates, cyanide, hexavalent chromium compounds, other oxidizers, reducers, combustible materials or flammable vapors.

PESTICIDE DISPOSAL: **Bottles:** If bottle contains less than 50 ml, empty contents into sink with running water according to local regulatory agency requirements or dispose as hazardous waste.

Bottles and Cassettes: Hydrogen peroxide is classified as a DOT oxidizer and a hazardous waste under US EPA hazardous waste regulation and it is a violation of Federal law to improperly dispose of pesticides. If these wastes cannot be disposed of by use or according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: **Cassettes:** Discard empty container per hospital policy.

Bottles: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

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STERRAD®

HYDROGEN PEROXIDE AQUEOUS SOLUTION STERILANT

FOR USE IN THE STERILIZATION OF
LABORATORY AND INDUSTRIAL EQUIPMENT

KEEP OUT OF REACH OF CHILDREN
DANGER

See Side Panel For Additional Precautionary Statements

STATEMENT OF PRACTICAL TREATMENT

If In Eyes: Hold eye open and rinse slowly and gently with water for 15 - 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

If On Skin or Clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 - 20 minutes.

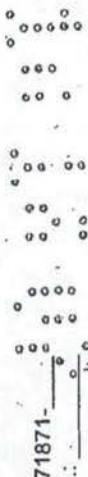
If Swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor.

Do not give anything by mouth to an unconscious person.
If Inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

Note To Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

ACTIVE INGREDIENT: Hydrogen peroxide 59.0%
INERT INGREDIENTS: 41.0%
TOTAL: 100.0%

EPA Registration No.: 71871-
EPA Establishment No.: 

Net Contents: _____

LOT: _____

PRECAUTIONARY STATEMENTS

DANGER. CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Do not breathe vapor or spray mist. Wear protective eyewear (goggles, face shield or safety glasses) and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash clothing before reuse.

PHYSICAL AND CHEMICAL HAZARDS.


Hydrogen peroxide is a strong oxidizing agent and poses a hazard for fire, explosion or container rupture. Avoid contact with contamination or combustible materials. Do not use or store near heat or open flame. Shoes, clothing, or other combustible materials that have come into contact with hydrogen peroxide must be immediately and thoroughly rinsed with water to avoid potential fire hazards. In case of fire, use only water. Contain spills and dilute with 20 parts of water. After diluting the contained spill, use sodium metabisulfite or sodium sulfite (1.9 lbs. SO₂ equivalent per 500 mL of spilled material) to deactivate the hydrogen peroxide.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to birds, mammals, fish and aquatic invertebrates. Do not charge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters, unless in accordance with the requirements of a National Pollutant Discharge Elimination System and the permitting authority has been notified in writing prior to discharge. Do not discharge this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Manufactured by:

ASP ADVANCED STERILIZATION PRODUCTS®

ACCEPTED  a Johnson & Johnson company
with COMMENTS
EPA Letter Dated: _____
Division of Ethicon, Inc.

CE

33 Technology Drive, Irvine, CA 92618-9824
(888) STERRAD

FEB 1 2008

Under the Federal Insecticide, Fungicide, and Rodenticide Act, amended, for the pesticide, registered under EPA Reg. No. 71871-3

Authorized EC Representative
Ethicon GmbH

©ASP, 2000

Expiration Date: (9 months from the date of manufacture will be inserted)

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

STERRAD® Hydrogen Peroxide is intended for sterilizing:

- tissue culture equipment and materials
- laboratory equipment (including glassware) and instrumentation
- medical instruments and devices in veterinary facilities

STERRAD® Hydrogen Peroxide may be used for treating items made of aluminum, brass, Delrin, ethyl vinyl acetate (EVA), glass, Kraton, latex, neoprene, nylon, Monel, polycarbonate, polyethylene, polystyrene, polypropylene, polyurethane, polyvinyl chloride (PVC), silicone, stainless steel, Teflon/polytetrafluoroethylene (PTFE)

For Use In The STERRAD® 200 Sterilizer Only.

Two (2) Cycles/Cassette

- Each cell contains not less than 0.0868 oz. (0.898 ± 0.003 oz.) [2466 mg (2550 ± 84 mg)] of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
- If the yellow indicator has turned red, the cassette might have been damaged. Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise:
- Remove plastic wrap from cassette sleeve. Do not remove cassette from the remaining cardboard packaging.
- Orient the arrow so that it is on top of the cassette sleeve and pointing away from you.
- Insert the cassette sleeve into the STERRAD® 200 Sterilizer.
- Push the cassette sleeve completely into the injector. Once properly positioned, the cassette will automatically be accepted and positioned for use by the Sterilizer. The monitor will read "Cassette Accepted." If the cassette is not accepted because the barcode cannot be read or the cassette has expired, the monitor will read "Please Remove Cassette." Should this occur, please insert a new cassette.
- When the cassette is empty or has reached its labeled expiration date, or has been in the machine 8 days (due to the higher temperature in the machine), it will automatically be re-inserted into the packaging and the monitor will display "Remove Cassette." Grasp and remove the sleeve containing the empty cassette. The chemical indicator on the cassette sleeve may have turned red due to the higher temperature in the machine.
- Discard the sleeves containing the empty cassettes as indicated in the disposal directions.
- If an UNUSED cassette extends or falls out of the sleeve, wear gloves to replace the cassette in the original sleeve and call ASP Customer Service.
- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® 200 Sterilizer cycle time is approximately 75 minutes.
- Refer to STERRAD® 200 Sterilizer System User's Guide for additional information.

ACCEPTED
with COMMENTS
EPA Letter Dated:

- OR -

For Use In The STERRAD® NX Sterilizer Only.

Five (5) Cycles/Cassette

- Each cell contains not less than 1750 ± 50 µL of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
- If the yellow indicator has turned red, the cassette might have been damaged. Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise:
- Remove plastic wrap from cassette sleeve. Do not remove cassette from the remaining cardboard packaging.
- Orient the arrow so that it is on top of the cassette sleeve and pointing away from you.
- Insert the cassette sleeve into the STERRAD® NX Sterilizer.
- Push the cassette sleeve completely into the injector. Once properly positioned, the cassette will automatically be accepted and positioned for use by the Sterilizer. The monitor will read "Cassette Accepted." If the cassette is not accepted because the barcode cannot be read or the cassette has expired, the monitor will read "Please Remove Cassette." Should this occur, please insert a new cassette.
- When the cassette is empty or has reached its labeled expiration date, or has been in the machine 8 days (due to the higher temperature in the machine), it will automatically be re-inserted into the packaging and the monitor will display "Remove Cassette." Grasp and remove the sleeve containing the empty cassette. The chemical indicator on the cassette sleeve may have turned red due to the higher temperature in the machine.
- Discard the sleeves containing the empty cassettes as indicated in the disposal directions.
- If an UNUSED cassette extends or falls out of the sleeve, wear gloves to replace the cassette in the original sleeve and call ASP Customer Service.

FEB 1 2008

Under the Federal Insecticide, Fungicide, and Rodenticide Act, this product is registered under EPA Reg. No. 71871-3

71871-3

4 7 359

- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® NX Sterilizer has two cycle times: the 28-minute Standard cycle is for most surgical instruments and the 38-minute Advance cycle is for the flexible endoscope.
- **Refer to STERRAD® NX Sterilizer System User's Guide for additional information.**

- OR -

For Use In The STERRAD® 50 Sterilizer Only.

Five (5) Cycles/Cassette

- Each cell contains not less than 0.592 fl. oz. (0.609 ± 0.017 fl. oz.) [(1750 µL (1800µL ± 50µL))] of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
- If the yellow indicator has turned red, the cassette might have been damaged. Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise:
- Remove plastic wrap from cassette sleeve. Do not remove cassette from the remaining cardboard packaging.
- Orient the arrow so that it is on top of the cassette sleeve and pointing away from you.
- Insert the cassette sleeve into the STERRAD® 50 Sterilizer.
- Push the cassette sleeve completely into the injector. Once properly positioned, the cassette will automatically be accepted and positioned for use by the Sterilizer. The monitor will read "Cassette Accepted." If the cassette is not accepted because the barcode cannot be read or the cassette has expired, the monitor will read "Please Remove Cassette." Should this occur, please insert a new cassette.
- When the cassette is empty or has reached its labeled expiration date, or has been in the machine 10 days (due to the higher temperature in the machine), it will automatically be re-inserted into the packaging and the monitor will display "Remove Cassette." Grasp and remove the sleeve containing the empty cassette. The chemical indicator on the cassette sleeve may have turned red due to the higher temperature in the machine.
- Discard the sleeves containing the empty cassettes as indicated in the disposal directions.
- If an UNUSED cassette extends or falls out of the sleeve, wear gloves to replace the cassette in the original sleeve and call ASP Customer Service.
- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® 50 Sterilizer cycle time is approximately 45 minutes.
- **Refer to STERRAD® 50 Sterilizer System User's Guide for additional information.**

- OR -

For Use In The STERRAD® 100S Sterilizer Only.

Five (5) Cycles/Cassette

- Each cell contains not less than 0.592 fl. oz. (0.609 ± 0.017 fl. oz.) [(1750 µL (1800µL ± 50µL))] of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
- If the yellow indicator has turned red, the cassette might have been damaged: Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise:
- Remove plastic wrap.
- Remove cassette from box.
- Insert the cassette sleeve into the STERRAD® 100S Sterilizer.
- The cassette will be accepted automatically.
- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® 100S Sterilizer cycle time is approximately 55 minutes.
- **Refer to STERRAD® 100S Sterilizer System User's Guide for additional information.**

ACCEPTED
with COMMENTS
EPA Letter Dated:

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

7/87/-3

This product is not to be used as a terminal-sterilant / high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: Store upright at all times. Keep product in its original packaging at a controlled room temperature, between 15° - 30°C (59° - 86°F). Do not expose product to direct sunlight, radiant heat, powdered metals, permanganates, cyanide, hexavalent chromium compounds, other oxidizers, reducers, combustible materials or flammable vapors.

PESTICIDE DISPOSAL: Bottles: If bottle contains less than 50 mL, empty contents into sink with running water according to local regulatory agency requirements or dispose as hazardous waste. **Bottles and Cassettes:** Hydrogen peroxide is classified as a DOT oxidizer and a hazardous waste under US EPA hazardous waste regulation and it is a violation of Federal law to improperly dispose of pesticides. If these wastes cannot be disposed of by use or according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.
CONTAINER DISPOSAL: **Cassettes:** Discard empty container per the policy of the institution or facility. **Bottles:** Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

ACCEPTED
with COMMENTS
EPA Letter Dated:

FEB 1 2008

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

71871-3

6 7 359

MATERIAL TO BE ADDED TO JACKET

REG #

71871-3

Description:

New Prig

check all that apply	
<input type="checkbox"/>	new stamped accepted label
<input type="checkbox"/>	new CSF
<input type="checkbox"/>	notification

Send to CSC

Instructions:

Attach this sheet to the top of **ALL** material sent to the file room (both loose paper and new material in jackets). This sheet will be imaged; a clear description will aid in finding material in the e-jacket. Remove staples from all material. If returning loose paper then hold together with a binder or paper clip. CSFs should be placed in the CSF folder (if returning jacket) or covered with a red CBI sheet (if returning loose paper). Material to be returned to file room should be place in the appropriate bin.

Reviewer's

Name:

M Levy

Date:

2/20/08

Phone:

308-6317

Division:

AD

Explore Registrations				
Reg Number:	71871-G		Reg. Type:	Product Registration - Section 3
Status:	Under Review (21-Nov-2006)			
Name:	STERRAD HYDROGEN PEROXIDE			<View Registration Details>
(No New Receipts)				
S:	Submission Type	OPP Rec'd Date	Resubmission	Description
<div> <div>...Decisions...</div> <div> <div>Data Requirements</div> <div> <div>D: Pending; 372392; 71871-G; A54; NEW PRODU</div> <div> <div>(ALERT) S: 818389 10/16/2007; Miscellaneous</div> <div> <div>DP 346220; AD / RMB1; Complete Date</div> <div> <div>(ALERT) S: 817516 9/11/2007; New Registr</div> <div> <div>DP 344717; AD / RMB1; Complete Date</div> <div> <div>S: 801691 11/21/2006; New Registration; 7</div> <div> <div>DP 335345; AD / RMB1; Complete Date</div> <div> <div>DP 335346; AD / RMB1; Complete Date</div> </div> </div> </div> </div> </div> </div> </div></div></div></div>		<div>Decision Sequence: 372392</div> <div>Action: A54 NEW PRODUCT; NON-FAST TRACK; FIFRA SEC. 2(M</div> <div>Number: 71871-G Original Decision:</div> <div>Name: STERRAD HYDROGEN PEROXIDE</div> <div>Decision Status: PENDING (28-Nov-2006)</div> <div>Organization Owner: AD / RMB1</div> <div>Team Owner: RM 33</div> <div>FFS Start Date: 12-Dec-2006 Received by Risk Manager:</div> <div>Due Date: 11-Apr-2007 FFS Amt Expected: \$4,200</div> <div>Negotiated Due Date: 01-Feb-2008 FFS Amt Refunded:</div> <div>FFS Amt Received: \$4,200</div> <div>Comments:</div>		

Martha Leary
Free Rd

FEB 1 2008

DECISION PKG. NO. 372392
SUBMISSION BAR CODE # 818389

SUBM. DUE DATE 2/1/08
REVIEWER MJ

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 71871-G PM 33 ACTION CODE PRIA ✓
DESCRIPTOR New RDTA **FQPA** **NFQPA**

[] CHILD RESISTANT PACKAGING: [] REQUIRED [] NOT REQUIRED
REGISTRATION TYPE: [] CONDITIONAL [] UNCONDITIONAL [] RESTRICTED USE

DATE ON APPLICATION
10, 08, 07

EPA RECEIVE DATE
10, 16, 08

PM RECEIVE DATE
10, 17, 07

METHOD OF SUPPORT

FORMULATORS EXEMPTION

[] CITE-ALL [] SELECTIVE
[] NOT SUBMITTED [] N/A

[] SUBMITTED [] NOT SUBMITTED
[] N/A

REVIEW(S) REQUESTED	DATA PACK #	DATE SENT	DUE DATE	DATE RETURNED
CHEMISTRY				
EFFICACY				
ACUTE TOX.				
RASSB TOX.				
ENVIRON. FATE				
FISH/WILDLIFE				
OTHER:				

STATUS _____

RESPONSE CODE 1160

RESPONSE DATE 2/1/08



U.S. ENVIRONMENTAL PROTECTION
AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510C)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration

(under FIFRA, as amended)

EPA Reg. Number:

71871-3

Date of Issuance:

FEB 1 2008

Term of Issuance:

Conditional

Name of Pesticide Product: **Sterrad**
Hydrogen Peroxide

Name and Address of Registrant (include ZIP Code):

Advanced Sterilization Products
33 Technology Drive
Irving, CA 92618

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.

2. Make the labeling changes listed below before you release the product for shipment:

a. Revise the "EPA Registration Number to read, "EPA Reg. No. 71871-3".

Signature of Approving Official:

Marshall Swindell
Product Manager Team-33
Regulatory Management Branch I
Antimicrobials Division (7510P)

Date:

FEB 1 2008

b. The User Guides must be revised in accordance with the comments listed on the 1/9/08 Efficacy Review. A copy is enclosed for your guidance.

2. Submit two (2) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the "accepted" label is enclosed for your records.

If you have any questions concerning this Notice, please contact Martha Terry at (703) 308-6217.

Sincerely,

A handwritten signature in blue ink, appearing to read "M. Swindell", is written over a faint, larger version of the same signature.

Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobials Division (7510P)

Enclosure

STERRAD®

HYDROGEN PEROXIDE
AQUEOUS SOLUTION STERILANT

FOR USE IN THE STERILIZATION OF
LABORATORY AND INDUSTRIAL EQUIPMENT

KEEP OUT OF REACH OF CHILDREN
DANGER

See Side Panel For Additional Precautionary Statements

STATEMENT OF PRACTICAL TREATMENT

If In Eyes: Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

If On Skin or Clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes.

If Swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

If Inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

Note To Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

ACTIVE INGREDIENT: Hydrogen peroxide 59.0%
INERT INGREDIENTS: 41.0%
TOTAL: 100.0%

EPA Registration No.: 71871-
EPA Establishment No.: 38

Net Contents: _____

LOT: _____

PRECAUTIONARY STATEMENTS

DANGER. CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Do not breathe vapor or spray mist. Wear protective eyewear (goggles, face shield or safety glasses) and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash clothing before reuse.

PHYSICAL AND CHEMICAL HAZARDS.

Hydrogen peroxide is a strong oxidizing agent and poses a hazard for fire, explosion or container rupture. Avoid contact with contamination or combustible materials. Do not use or store near heat or open flame. Shoes, clothing, or other combustible materials that have come into contact with hydrogen peroxide must be immediately and thoroughly rinsed with water to avoid potential fire hazards. In case of fire, use only water. Contain spills and dilute with 20 parts of water. After diluting the contained spill, use sodium metabisulfide or sodium sulfite (1.9 lbs. SO₂ equivalent per 500 mL of spilled material) to deactivate the hydrogen peroxide.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to birds, mammals, fish and aquatic invertebrates. Do not charge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System and the permitting authority has been notified in writing prior to discharge. Do not discharge this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Manufactured by:

ASP ADVANCED STERILIZATION PRODUCTS®
ACCEPTED a Johnson & Johnson company
with COMMENTS Division of Ethicon, Inc.



EPA Letter Dated: Technology Drive, Irvine, CA 92618-9824
(888) STERRAD

FEB 1 2008

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide, registered under EPA Reg. No. 71871-33

Authorized EC Representative
Ethicon GmbH
Poststraße 1, D-22844 Norderstedt

©ASP, 2000

Expiration Date: (9 months from the date of manufacture will be inserted)

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

STERRAD® Hydrogen Peroxide is intended for sterilizing:

- tissue culture equipment and materials
- laboratory equipment (including glassware) and instrumentation
- medical instruments and devices in veterinary facilities

STERRAD® Hydrogen Peroxide may be used for treating items made of aluminum, brass, Delrin, ethyl vinyl acetate (EVA), glass, Kraton, latex, neoprene, nylon, Monel, polycarbonate, polyethylene, polystyrene, polypropylene, polyurethane, polyvinyl chloride (PVC), silicone, stainless steel, Teflon/polytetrafluoroethylene (PTFE)

For Use In The STERRAD® 200 Sterilizer Only.

Two (2) Cycles/Cassette

- Each cell contains not less than 0.0868 oz. (0.898 ± 0.003 oz.) [2466 mg (2550 ± 84 mg)] of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
- If the yellow indicator has turned red, the cassette might have been damaged. Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise:
- Remove plastic wrap from cassette sleeve. Do not remove cassette from the remaining cardboard packaging.
- Orient the arrow so that it is on top of the cassette sleeve and pointing away from you.
- Insert the cassette sleeve into the STERRAD® 200 Sterilizer.
- Push the cassette sleeve completely into the injector. Once properly positioned, the cassette will automatically be accepted and positioned for use by the Sterilizer. The monitor will read "Cassette Accepted." If the cassette is not accepted because the barcode cannot be read or the cassette has expired, the monitor will read "Please Remove Cassette." Should this occur, please insert a new cassette.
- When the cassette is empty or has reached its labeled expiration date, or has been in the machine 8 days (due to the higher temperature in the machine), it will automatically be re-inserted into the packaging and the monitor will display "Remove Cassette." Grasp and remove the sleeve containing the empty cassette. The chemical indicator on the cassette sleeve may have turned red due to the higher temperature in the machine.
- Discard the sleeves containing the empty cassettes as indicated in the disposal directions.
- If an UNUSED cassette extends or falls out of the sleeve, wear gloves to replace the cassette in the original sleeve and call ASP Customer Service.
- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® 200 Sterilizer cycle time is approximately 75 minutes.
- Refer to STERRAD® 200 Sterilizer System User's Guide for additional information.

- OR -

For Use In The STERRAD® NX Sterilizer Only.

Five (5) Cycles/Cassette

- Each cell contains not less than 1750 ± 50 µL of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
- If the yellow indicator has turned red, the cassette might have been damaged. Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise:
- Remove plastic wrap from cassette sleeve. Do not remove cassette from the remaining cardboard packaging.
- Orient the arrow so that it is on top of the cassette sleeve and pointing away from you.
- Insert the cassette sleeve into the STERRAD® NX Sterilizer.
- Push the cassette sleeve completely into the injector. Once properly positioned, the cassette will automatically be accepted and positioned for use by the Sterilizer. The monitor will read "Cassette Accepted." If the cassette is not accepted because the barcode cannot be read or the cassette has expired, the monitor will read "Please Remove Cassette." Should this occur, please insert a new cassette.
- When the cassette is empty or has reached its labeled expiration date, or has been in the machine 8 days (due to the higher temperature in the machine), it will automatically be re-inserted into the packaging and the monitor will display "Remove Cassette." Grasp and remove the sleeve containing the empty cassette. The chemical indicator on the cassette sleeve may have turned red due to the higher temperature in the machine.
- Discard the sleeves containing the empty cassettes as indicated in the disposal directions.
- If an UNUSED cassette extends or falls out of the sleeve, wear gloves to replace the cassette in the original sleeve and call ASP Customer Service.

FEB 1 2008

Under the Federal Insecticide, Fungicide, and Rodenticide Act, this product is hereby declared to be a pesticide, registered under EPA Reg. No. 71871-3

ACCEPTED
with COMMENTS
EPA Letter Dated:

- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® NX Sterilizer has two cycle times: the 28-minute Standard cycle is for most surgical instruments and the 38-minute Advance cycle is for the flexible endoscope.
- **Refer to STERRAD® NX Sterilizer System User's Guide for additional information.**

- OR -

For Use In The STERRAD® 50 Sterilizer Only.

Five (5) Cycles/Cassette

- Each cell contains not less than 0.592 fl. oz. (0.609 ± 0.017 fl. oz.) [(1750 µL (1800µL ± 50µL))] of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
- If the yellow indicator has turned red, the cassette might have been damaged. Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise:
- Remove plastic wrap from cassette sleeve. Do not remove cassette from the remaining cardboard packaging.
- Orient the arrow so that it is on top of the cassette sleeve and pointing away from you.
- Insert the cassette sleeve into the STERRAD® 50 Sterilizer.
- Push the cassette sleeve completely into the injector. Once properly positioned, the cassette will automatically be accepted and positioned for use by the Sterilizer. The monitor will read "Cassette Accepted." If the cassette is not accepted because the barcode cannot be read or the cassette has expired, the monitor will read "Please Remove Cassette." Should this occur, please insert a new cassette.
- When the cassette is empty or has reached its labeled expiration date, or has been in the machine 10 days (due to the higher temperature in the machine), it will automatically be re-inserted into the packaging and the monitor will display "Remove Cassette." Grasp and remove the sleeve containing the empty cassette. The chemical indicator on the cassette sleeve may have turned red due to the higher temperature in the machine.
- Discard the sleeves containing the empty cassettes as indicated in the disposal directions.
- If an UNUSED cassette extends or falls out of the sleeve, wear gloves to replace the cassette in the original sleeve and call ASP Customer Service.
- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® 50 Sterilizer cycle time is approximately 45 minutes.
- **Refer to STERRAD® 50 Sterilizer System User's Guide for additional information.**

- OR -

For Use In The STERRAD® 100S Sterilizer Only.

Five (5) Cycles/Cassette

- Each cell contains not less than 0.592 fl. oz. (0.609 ± 0.017 fl. oz.) [(1750 µL (1800µL ± 50µL))] of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
- If the yellow indicator has turned red, the cassette might have been damaged. Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise:
- Remove plastic wrap
- Remove cassette from box.
- Insert the cassette sleeve into the STERRAD® 100S Sterilizer.
- The cassette will be accepted automatically.
- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® 100S Sterilizer cycle time is approximately 55 minutes.
- **Refer to STERRAD® 100S Sterilizer System User's Guide for additional information.**

ACCEPTED
with COMMENTS
EPA Letter Dated:

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

71871-3

This product is not to be used as a terminal sterilant / high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: Store upright at all times. Keep product in its original packaging at a controlled room temperature, between 15° - 30°C (59° - 86°F). Do not expose product to direct sunlight, radiant heat, powdered metals, permanganates, cyanide, hexavalent chromium compounds, other oxidizers, reducers, combustible materials or flammable vapors.

PESTICIDE DISPOSAL: **Bottles:** If bottle contains less than 50 mL, empty contents into sink with running water according to local regulatory agency requirements or dispose as hazardous waste. **Bottles and Cassettes:** Hydrogen peroxide is classified as a DOT oxidizer and a hazardous waste under US EPA hazardous waste regulation and it is a violation of Federal law to improperly dispose of pesticides. If these wastes cannot be disposed of by use or according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: **Cassettes:** Discard empty container per the policy of the institution or facility. **Bottles:** Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

ACCEPTED
with COMMENTS
EPA Letter Dated:

FEB 1 2008

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

71871-G-3

LEWIS & HARRISON

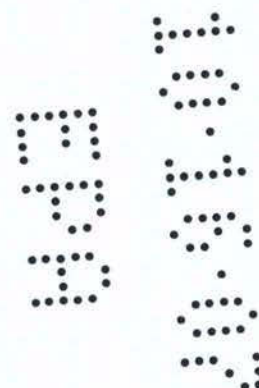
Consultants in Government Affairs

122 C Street, N.W., Suite 740
Washington, D.C. 20001

telephone 202.393.3903
fax 202.393.3906

October 8, 2007

Marshall Swindell, Product Manager (33)
Regulatory Management Branch #1
Antimicrobials Division (7510P)
Office of Pesticide Programs
Environmental Protection Agency
One Potomac Yards
2777 S. Crystal Drive
Arlington, VA



re: **STERRAD® Hydrogen Peroxide**
EPA File Symbol No. 71871-G
Registrant: Advanced Sterilization Products
Agency Letters Dated March 22, 2007 and July 30, 2007
Registration Application for New End-Use Product

Dear Marshall:

On behalf of Advanced Sterilization Products (ASP), I am responding to the Agency's letters of March 22, 2007 and July 30, 2007. As indicated at our meeting on May 15, 2007 and in follow-up e-mails of May 22, 2007 and June 19, 2007 (refer to Attachment 1), ASP is providing the following data/information:

- 1) Sterilant efficacy data for two additional lots of STERRAD Hydrogen Peroxide using the STERRAD 100S Sterilization System. Previously, ASP had provided studies on additional lots of STERRAD Hydrogen Peroxide using the STERRAD 100S system. As noted in the Agency's e-mail of June 19, 2007, a confirmatory study is not necessary.
2. A comparison of the different STERRAD Sterilization Systems and justification for using the STERRAD 100S unit as a "worst-case" surrogate (refer to Attachment 2).

3. Clarification of the two Good Laboratory Practice (GLP) deficiencies that were noted in the GLP compliance page for the study "AOAC Sporocidal Activity of Disinfectants Test in the STERRAD 100S Sterilization System for EPA Registration Using STERRAD Hydrogen Peroxide", MRID 46992802 (refer to Attachment 3).
4. Summary of efficacy studies conducted with STERRAD Hydrogen Peroxide (refer to Attachment 4).
5. Background information on the product chemistry issues (refer to Attachment 5).

In addition, please find enclosed five (5) copies of a revised label in accordance with the Agency's March 22, 2007 correspondence.

If you have any questions about this submission, please contact me at (202) 593-3903, ext. 14.

Sincerely,



Eliot Harrison
Agent for Advanced
Sterilization Products



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 17, 2007

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

ADVANCED STERILIZATION PRODUCTS
122 C ST NW STE 740
WASHINGTON, DC 20001

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 16-OCT-07. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Receipt for Section 3

S: 818389

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Miscellaneous Receipt

Billable: ☐ Yes ☒ No

Company: 71871 ADVANCED STERILIZATION PRODUCTS

V

Print Letter

Enter More Information

Tracking

Risk Manager: Antimicrobials Division, Risk Management Team 33

Product #: 71871-G

Product Name: STERRAD HYDROGEN PEROXIDE

Override:

Me Too

Me Too

Section3:

Product Name:

Application Date: 08-Oct-2007

ie

OPP Rec'd Date: 16-Oct-2007

ie

Front End Date: 17-Oct-2007

ie

Risk Manager Send Date: 17-Oct-2007

ie

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Receipt Content

Study

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

response to Agency letters of 3/22/07 and 7/30/07

New Ingredient

Request Date:

New Ingredient

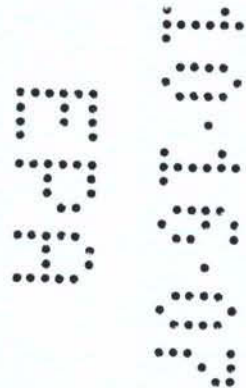
Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:



ATTACHMENT 1

E-mail Correspondence Regarding Registration Application for
STERRAD Hydrogen Peroxide

Eliot Harrison

To: Edwards.Dennis@epamail.epa.gov
Subject: RE: FW: Sterrad Hydrogen Peroxide, 71871-G

-----Original Message-----

From: Edwards.Dennis@epamail.epa.gov
[mailto:Edwards.Dennis@epamail.epa.gov]
Sent: Tuesday, June 19, 2007 1:00 PM
To: Eliot Harrison
Cc: Swindell.Marshall@epamail.epa.gov; Blackburn.Tajah@epamail.epa.gov
Subject: Re: FW: Sterrad Hydrogen Peroxide, 71871-G

Eliot,

The previous studies will satisfy the confirmatory efficacy requirement for this product.

Dennis Edwards
Antimicrobials Division
703-308-8087

"Eliot Harrison"
<eharrison@lewis
harrison.com>

06/13/2007 02:27
PM

Marshall
Swindell/DC/USEPA/US@EPA, Dennis
Edwards/DC/USEPA/US@EPA

To

cc

Subject

FW: Sterrad Hydrogen Peroxide,
71871-G

Marshall,

The ASP folks will let me know tomorrow regarding the scheduling of the additional efficacy studies (2 or 3 lots, depending on whether a confirmatory is required). I should have the comparison chart by the end of the week, which I will forward along with the GLP deficiency issue.

Eliot

-----Original Message-----

From: Eliot Harrison
Sent: Tuesday, May 22, 2007 12:10 PM
To: 'swindell.marshall@epa.gov'; 'edwards.dennis@epa.gov'

Subject: Sterrad Hydrogen Peroxide, 71871-G

Dennis,

As a follow-up to our meeting last week, below is my understanding of the additional data/information that ASP will have to provide for the above product:

- 1) Sterilant efficacy data for 2 additional lots of the product. This study will be conducted in accordance with GLP standards using the AOAC Sporicidal protocol.
- 2) Additional information on the two GLP deficiencies that were noted on the GLP Compliance page. These deficiencies are as follows: "Data for Maintenance of Cultures was not recorded in compliance with GLP requirements" and "Data for Propagation and Harvesting of Bacterial Cultures were Not Recorded Promptly as per GLP"
- 3) A comparison chart of the different ASP sterilizer units and a justification that the "100S" unit is "worst-case" for efficacy testing.

The Agency will let ASP know if the confirmatory efficacy study can be satisfied by the previously submitted efficacy studies provided by ASP or whether a confirmatory is required. If a confirmatory is required, the study can be conducted at the same lab as long as there is a different study director.

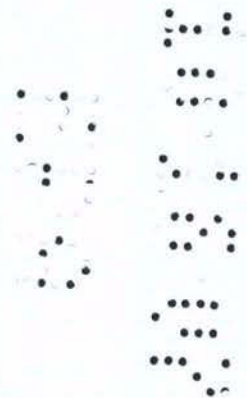
Finally, can you check with Juan Negron on the outstanding chemistry issues. If additional data is needed, we need to know ASAP so these can be submitted with the efficacy data.

Let me know if I missed anything.

Eliot

ATTACHMENT 2

Comparison of Different STERRAD Sterilization System Units
and Justification for Using STERRAD 100S as a "Worst-Case" Surrogate



Introduction

During the meeting held between Advanced Sterilization Products (ASP) and Antimicrobials Division (AD) staff on May 16, 2007, AD requested a comparison chart of the various STERRAD[®] hydrogen peroxide sterilizer units, with an emphasis on the differences in the specific cycle parameters. This document provides the requested information. In addition, AD requested that ASP provide a justification for the use of the STERRAD 100S sterilizer unit as a "worst-case" surrogate for the other STERRAD sterilization units. This justification is presented on page 9 of this document.

Background

The STERRAD hydrogen peroxide sterilizer units are low temperature (capable of processing loads sensitive to more than 50 deg. C), self-contained, stand-alone systems of hardware and software designed to sterilize equipment using a patented hydrogen peroxide gas plasma process. Hydrogen peroxide vapor is generated by injecting aqueous hydrogen peroxide into the vaporizer bowl where the solution is heated and transformed into a vapor, then introducing the vapor into the process chamber under sub-ambient pressure and finally transforming the vapor into a gas-plasma with electricity. The sterilization process is the entire sequence of operations, based upon liquid hydrogen peroxide injection and plasma generation.

The STERRAD sterilization cycle consists of two half-cycles, with each half-cycle including a hydrogen peroxide injection phase. When hydrogen peroxide is injected into the chamber during each half-cycle, a rise in pressure is observed. However, several steps in the STERRAD sterilization process require a very low pressure. To achieve this low pressure, a vacuum pump system is used. With the vacuum pump systems that are used, the moisture content of the evacuated air can affect pumping efficiency (i.e., the time to reach the required low pressure levels). To ensure that the required pressure is attained within the specified time, a Pre-Exposure Plasma phase is used at the beginning of the process and before the first injection/diffusion/plasma phase in order to remove the excess surface moisture on the sterilization load.

Operation the Sterilizer Units

The STERRAD[®] sterilizer process consists of four steps.

Phase 1- Pre-Exposure Plasma

Phase 2 – Exposure 1

Phase 3 - Exposure 2

Phase 4 – Post Processing

A detailed explanation of each phase is presented below.

Phase 1 - Pre-Exposure Plasma

The Pre-Exposure Plasma phase consists of four steps: initial vacuum, air plasma, vent 1, and vacuum.

Phase 1 - Step 1

Initial Vacuum:

After the STERRAD® sterilizer unit has been loaded and the door closed, the sterilization process begins with evacuation of atmospheric pressure from the chamber through the use of a vacuum pump.

Phase 1 - Step 2

Air Plasma:

After reaching the specified pressure level, the plasma power is turned on and electrical energy is supplied to the electrode screen. The energy field creates air plasma in the chamber, which lasts between 10 to 20 minutes depending upon the sterilizer unit. The term air plasma is used because the plasma involves only the residual air in the process chamber following the previous evacuation step. The purpose of this air plasma step is to assist in removing residual surface moisture by accelerating its vaporization and allowing it to be removed from the chamber by the vacuum pump.

Phase 1- Step 3

Vent 1:

At the end of the air plasma step, the chamber is vented to atmospheric pressure with filtered air.

Phase 1- Step 4

Vacuum:

After reaching atmospheric pressure, the chamber pressure is reduced to specific pressure, depending upon the sterilizer unit, in preparation for Phase 2 of the process.

Phase 2 – Exposure 1

The Exposure 1 phase consists of five steps: injection 1, diffusion 1, vacuum, plasma 1, and vacuum. This phase is the first of the two sequential exposure phases.

Phase 2- Step 1

Injection 1:

When the chamber reaches the specific pressure (depending upon the sterilizer type), either one or two (depending upon the sterilizer unit) unused cassette cells are punctured sequentially by the injector needle. The contents of the cells (aqueous hydrogen peroxide at @ 59%) are transferred through the injector mechanism into the vaporization bowl, where the hydrogen peroxide is vaporized and introduced into the evacuated process chamber. The positioning of the cassette and the injection step are monitored and controlled by the software. After the first cell of hydrogen peroxide is pierced, the cassette mechanism requires 15 seconds of indexing time before the second cell is pierced (this is only true for the STERRAD 200 Sterilizer)

Phase 2- Step 2

Diffusion 1:

Following the injection step, the chamber is vented to atmospheric pressure with filtered air.

Phase 2- Step 3

Vacuum:

Following diffusion, the chamber is evacuated to its required pressure depending upon the sterilizer unit in preparation for the plasma 1 step.

Phase 2- Step 4

Plasma 1:

Following process chamber evacuation, the gas plasma step begins. The first step in the process is the lighting of the plasma. Following plasma light, plasma power is applied to the electrode screen. This step produces a series of reactions in the hydrogen peroxide vapor leading to generation and acceleration of charged particles, generating free radicals and other reactive chemical species.

Phase 2- Step 5

Vacuum:

At the conclusion of the plasma 1 step, the chamber is evacuated to its sterilizer unit specific pressure.

Phase 3 - Exposure 2

The Exposure 2 phase is identical to Exposure 1 phase, except the last step (additional vacuum step) is omitted. Therefore, this phase is the second of the two sequential exposure phases.

Phase 3 -Step 1

Injection 2 - (Identical to phase 2)

When the chamber reaches the specific pressure (depending upon the sterilizer unit), either one or two (depending upon the sterilizer unit) unused cassette cells are punctured sequentially by the injector needle. The contents of the cells (aqueous hydrogen peroxide at @ 59%) are transferred through the injector mechanism into the vaporization bowl, where the hydrogen peroxide is vaporized and introduced into the evacuated process chamber. The positioning of the cassette and the injection step are monitored and controlled by the software. After the first cell of hydrogen peroxide is pierced, the cassette mechanism requires 15 seconds of indexing time before the second cell is pierced (this is only true for the STERRAD 200 Sterilizer)

Phase 3 -Step 2

Diffusion 2 - (Identical to phase 2)

Following the injection step, the process chamber is vented to atmospheric pressure with filtered air.

Phase 3 –Step 3

Vacuum - (Identical to phase 2):

Following diffusion, the process chamber is again evacuated to its specific pressure depending upon sterilizer in preparation for the plasma 2 step.

Phase 3 –Step 4

Plasma 2 - (Identical to phase 2)

Phase 4 – Post Processing

In the post-processing phase, the process residuals are removed from the surface of instruments and packaging and the process chamber is vented to atmospheric pressure. These are the final steps of the process and the final venting step allows the chamber door to be opened.

Phase 4 –Step 1

Vent Hold: (Phase 4 – steps 1 to 3 apply on to the STERRAD 200 sterilizer)

After completion of Plasma 2, the chamber is vented to the atmosphere to allow convection heat transfer from the electrode surface to the objects being sterilized on the shelves. The heat transfer enhances desorption of residual hydrogen peroxide on the object's surface.

Phase 4 –Step 2

Vacuum:

Following vent hold, the process chamber is again evacuated to its specific pressure in preparation for the vacuum hold step.

Phase 4 –Step 3

Vacuum Hold

The vacuum within the chamber is held to a specific pressure for sufficient time to remove residual hydrogen peroxide from the chamber and from the surfaces of the product being sterilized.

Phase 4 –Step 4 (This step applies to STERRAD 50, STERRAD 100S And the STERRAD 200 sterilizers)

Vent Final

In the final venting phase, the process chamber is vented to atmospheric pressure. This is the final step of the process and allows the chamber door to be opened.

A comparison of the parameters for each of the STERRAD sterilizer unit are shown in Table 1 below.

Table 1:
Variance of the Process Parameters of the Sterilizers - STERRAD 50,
STERRAD 100S, STERRAD 200

Phase	Variable	STERRAD 50	STERRAD 100S	STERRAD 200	Explanation for the Variance
Phase 1	Pressure	≤800 mTorr	≤700 mTorr	700 mTorr (+50/-150 mTorr)	The pressure is necessary for the ignition and maintenance of the plasma. The variance in the pressure is due to different chamber size configuration.
	Plasma Time	15 min.	10 min	20 min	Plasma time is longer for the STERRAD 200 unit due to its larger chamber size
	Temperature	45°C	45°C	49°C	Temperature is higher for the STERRAD 200 unit to drive off the moisture within the larger size chamber.
	Plasma Power	400 watts	400 watts	485 watts	The delivered power is increased for the STERRAD 200 unit due its larger size chamber and more energy is required to remove moisture from the load since it holds larger load.

Phase 2	Pre injection Pressure	≤ 400 mTorr	≤ 400 mTorr	600 mTorr	The purpose of the pressure differential for the STERRAD 200 unit is to save operational time. No impact on efficacy.
	Plasma Pressure	500 mTorr	500 mTorr	600 mTorr	Plasma pressure optimized for the configuration of the larger chamber size for the STERRAD 200 unit.
	Injection Time	6.5 min.	6 min	6 minutes 45 seconds	The difference in injection time for the STERRAD 50 and STERRAD 100S units is an inadvertent artifact from their software developments (both were intended to be 6 minutes). The use of 6.5 minutes for the STERRAD 50 was discovered only after all the validation was completed and no difference was noted between the two sterilizers. The STERRAD 200 unit uses 6 minutes 45 seconds for injection as 2 cells of hydrogen peroxide are injected for each half cycle whereas STERRAD 100S and STERRAD 50 uses one cell of hydrogen peroxide. The additional time is needed for indexing of the cassette and the injection of the 2 cells of hydrogen peroxide.
	Temperature	45°C	45°C	49°C	Higher temperature for the STERRAD 200 unit is to optimize the cycle efficacy.
	Vaporizer/Tube Temperature	NA	NA	70°C	To optimize the cycle efficacy of STERRAD 200 unit.

Phase 3	Pre injection Pressure	≤ 400 mTorr	≤ 400 mTorr	600 mTorr	The purpose of the pressure differential for the STERRAD 200 unit is to save operational time.
	Plasma Pressure	500 mTorr	500 mTorr	600 mTorr	More plasma pressure optimized the configuration of the STERRAD 200 vessel.
	Injection Time	6.5 min	6 min	6 minutes 45 seconds	The time difference in injection time for the STERRAD 50 and STERRAD 100S units is because their software was set up at different times and validated accordingly. The STERRAD 200 uses 6 minutes 45 seconds for injection as 2 cells of hydrogen peroxide are injected for each half cycle whereas the STERRAD 100S and STERRAD 50 units use one cell of hydrogen peroxide. The additional time is needed for indexing of the cassette and the injection of the 2 cells of hydrogen peroxide.
	Temperature	45°C	45°C	49°C	Higher temperature optimizes the cycle the efficacy for the STERRAD 200 unit.
	Vaporizer/Tube Temperature	NA	NA	70°C	To optimize the cycle the efficacy of the STERRAD 200 unit.

Phase 4	Vent to Atmospheric Pressure - Time	1 Step Process; 1 minute	1 Step Process; 1 minute	Multi-Step Process; ≤ 26 minutes	Since the STERRAD 200 unit can hold larger loads, this allows convection heat transfer from electrode surface to the objects being sterilized on the shelf. The heat transfer enhances desorption of residual hydrogen peroxide on the load's surface.
				The chamber is vented and held at atmospheric pressure for 5 minutes.	
				A vacuum is then pulled on the chamber for a pressure of 600 mTorr max. The vacuum is held at 600 \pm 400 mTorr for 10 minutes.	Following vent hold, the process chamber of the STERRAD 200 unit is pumped down to 600 mTorr and held for 10 minutes to remove residual hydrogen peroxide from the chamber and surface of load being sterilized.
				The chamber is then brought to atmospheric pressure.	Residuals in the STERRAD 200 unit were found to be equivalent to those found in the STERRAD 50 and 100S.
Total Cycle Time		45	54	75	Increased cycle time is due to the extended pre-plasma time as well as the post-processing step of the STERRAD 200 unit, as a consequence of its larger chamber size and load capacity.

The minimum and maximum concentrations of hydrogen peroxide employed during the sterilization cycles for the various STERRAD sterilizer units is presented in Table 2 below. As shown in the chart, the lowest concentration of hydrogen peroxide that is used is for the STERRAD 100S unit. Accordingly, the STERRAD 100S unit can be considered “worst-case” for the STERRAD sterilization units.

Table 2
Hydrogen Peroxide Concentration in an Empty Chamber (Theoretical Values)

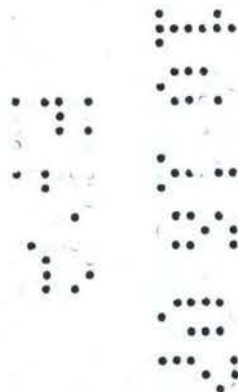
Sterilization System	Maximum Concentration of Hydrogen Peroxide Transferred per Half Cycle During a Full Sterilization Cycle*	Minimum Concentration of Hydrogen Peroxide Transferred per Half Cycle During a Full Sterilization Cycle*
STERRAD® 50	18.6 mg/L	14.3 mg/L
STERRAD® 100S	7.8 mg/L	6.0 mg/L
STERRAD® 200	11.7 mg/L	9.3 mg/L
STERRAD® NX**	22.1 mg/L	13.8mg/L

*The STERRAD 50, 100S and 200 values are based on the cassette fill volume as the entire contents of the cassette are delivered to the vaporizer.

**The STERRAD NX values are based on the mass of hydrogen peroxide solution in the condenser prior to transfer to the chamber.

ATTACHMENT 3

Clarification of Good Laboratory Practice (GLP) Issue with
Previously Submitted Efficacy Study



GOOD LABORATORY PRACTICE ISSUES

In the study entitled, "AOAC Sporicidal Activity of Disinfectants Test in the STERRAD 100S Sterilization System for EPA Registration Using STERRAD Hydrogen Peroxide", MRID No. 46992802, the Good Laboratory Practice (GLP) page made the following statement:

The study meets the requirements of 40 CFR Part 160. The study referenced in this report was conducted in compliance with the Good Laboratory Practices (GLP) Standards as published by the Environmental Protection Agency 40 CFR Part 160, dated August 17, 1989 with the following exceptions:

Data for maintenance of cultures was not recorded in compliance with the GLP regulations.

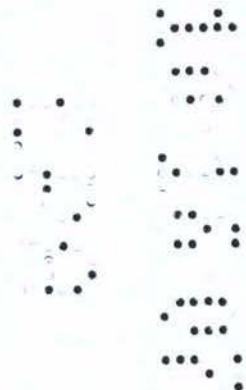
Data for propagation and harvesting of bacterial cultures were not recorded promptly as per GLP.

These GLP deficiencies were addressed on page 11 of the study report under the heading "Description of Circumstances". Specifically, it was stated:

- Apparatus ID was not recorded on worksheet for 7/10 and 7/19. The apparatus was a desiccator attached to a vacuum. Contaminated carriers were placed on sterile petri dishes in individually identified containers specific to appropriate bacterial strain. This should have no impact on the outcome of the study.
- The raw data sheets recorded the readings of all carriers tested after heat shock (performed after 21 days incubation) and did not record readings taken prior to heat shock. Per AOAC, heat shock is required only if there is no growth in the carriers tested. No growth was observed in all transfer tubes for all three (3) sterilization cycles prior to heat shock. No effect on the outcome of the study.
- Negative control results were checked and inadvertently not recorded on raw data sheets for sterilization cycle #3. The media lot numbers used (FTM and catalase reagent) for cycle #3 negative controls 3 were the same lot # as cycle #2; therefore, the missed negative control results reading had no effect on the outcome of the study.

ATTACHMENT 3

Clarification of Good Laboratory Practice (GLP) Issue with
Previously Submitted Efficacy Study



GOOD LABORATORY PRACTICE ISSUES

In the study entitled, "AOAC Sporidical Activity of Disinfectants Test in the STERRAD 100S Sterilization System for EPA Registration Using STERRAD Hydrogen Peroxide", MRID No. 46992802, the Good Laboratory Practice (GLP) page made the following statement:

The study meets the requirements of 40 CFR Part 160. The study referenced in this report was conducted in compliance with the Good Laboratory Practices (GLP) Standards as published by the Environmental Protection Agency 40 CFR Part 160, dated August 17, 1989 with the following exceptions:

Data for maintenance of cultures was not recorded in compliance with the GLP regulations.

Data for propagation and harvesting of bacterial cultures were not recorded promptly as per GLP.

These GLP deficiencies were addressed on page 11 of the study report under the heading "Description of Circumstances". Specifically, it was stated:

- Apparatus ID was not recorded on worksheet for 7/10 and 7/19. The apparatus was a desiccator attached to a vacuum. Contaminated carriers were placed on sterile petri dishes in individually identified containers specific to appropriate bacterial strain. This should have no impact on the outcome of the study.
- The raw data sheets recorded the readings of all carriers tested after heat shock (performed after 21 days incubation) and did not record readings taken prior to heat shock. Per AOAC, heat shock is required only if there is no growth in the carriers tested. No growth was observed in all transfer tubes for all three (3) sterilization cycles prior to heat shock. No effect on the outcome of the study.
- Negative control results were checked and inadvertently not recorded on raw data sheets for sterilization cycle #3. The media lot numbers used (FTM and catalase reagent) for cycle #3 negative controls 3 were the same lot # as cycle #2; therefore, the missed negative control results reading had no effect on the outcome of the study.

DECISION PKG. NO. 3723 92SUBM. DUE DATE 2/1/08 *new ext. date*SUBMISSION BAR CODE # 817516REVIEWER MT**CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS**FILE SYMBOL/REG NO. 71871-GPM 33ACTION CODE A-54DESCRIPTOR Resubmission**FQPA****NFQPA**☐ CHILD RESISTANT PACKAGING:☐ REQUIRED☐ NOT REQUIREDREGISTRATION TYPE: ☐ CONDITIONAL☐ UNCONDITIONAL☐ RESTRICTED USE

DATE ON APPLICATION

09/10/07

EPA RECEIVE DATE

09/11/07

PM RECEIVE DATE

09/14/07

METHOD OF SUPPORT

FORMULATORS EXEMPTION

☐ CITE-ALL☐ SELECTIVE☐ SUBMITTED☐ NOT SUBMITTED☐ NOT SUBMITTED☐ N/A☐ N/A

REVIEW(S) REQUESTED

DATA
PACK #DATE
SENTDUE
DATEDATE
RETURNED

CHEMISTRY _____

EFFICACY _____

ACUTE TOX. _____

RASSB TOX. _____

ENVIRON. FATE _____

FISH/WILDLIFE _____

OTHER: _____

STATUS _____

RESPONSE CODE _____

RESPONSE DATE _____

SCIENCE
GROUP

DIVISION

BRANCH

SECTION

CSF
Y/NLABEL
Y/NCHEMISTRY AD EASSB CTTEFFICACY AD EASSB EET

LEWIS & HARRISON

Consultants in Government Affairs

122 C Street, N.W., Suite 740
Washington, D.C. 20001

telephone 202.393.3903
fax 202.393.3906

September 10, 2007

Marshall Swindell, Product Manager (33)
Regulatory Management Branch Number 1
Antimicrobials Division (7510P)
Office of Pesticide Programs
Environmental Protection Agency
2777 S. Crystal Drive
Arlington, VA 22210

re: **Sterrad Hydrogen Peroxide**
EPA File Symbol No. 71871-G
Registrant: Advanced Sterilization Products
Your Letter Dated July 30, 2007

Dear Marshall:

On behalf of Advanced Sterilization Products (ASP), I am responding to your letter (attached) of July 30, 2007. Please note the following:

- 1) A new efficacy study with Sterrad Hydrogen Peroxide in a representative, "worst-case" sterilization system is currently being conducted. As noted in the attached e-mail, a confirmatory study will not be required. The new efficacy study will be submitted by October 1, 2007.
- 2) The required product chemistry studies were previously submitted to the Agency. Refer to the attached e-mail on this issue.
- 3) ASP is proposing a new PRIA completion date of February 1, 2008. This date takes into account the time for "front-end" processing of the new efficacy study and provides ninety (90) days for Agency review.

If you have any questions about this correspondence, please contact me at (202) 393-3903, ext. 14.

Sincerely,



Eliot Harrison
Agent for Advanced Sterilization Products

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 30 2007



United States
Environmental Protection
Agency

Office of Pesticide Programs

OPP Decision Number: D-372392

Ana Rodriguez-Koster
Advanced Sterilization Products
33 Technology Drive
Irvine, CA 92618

AGENT: Lewis & Harrison
122 C Street, N. W., Suite 740
Washington, D. C. 20001

Subject: Product Name: Sterrad Hydrogen Peroxide
EPA File Symbol: 71871-G
Application Date: November 2, 2006

Our records indicate that the decision review period for EPA to make a determination regarding the above referenced application ends on 10/11/07 as pursuant to the Pesticide Registration Improvement Act (PRIA). The application has been determined, pursuant to 40 CFR 152.105, not to be sufficiently complete to process; therefore, the application is considered deficient. Information as specified below must be submitted before the processing of the application can be completed. If such deficiencies cannot be corrected within 75 days from the date of this letter, you must notify the Agency by 11/1/07. Include an explanation of why it will take longer to submit the requested information, including your schedule to respond to the deficiencies and a request for a negotiated PRIA due date.

If, after 75 days from the date of this letter, you do not respond, or you subsequently fail to submit a completed application within the time scheduled for completion, the Agency will terminate any action on the application, and will treat the application as if it has been withdrawn by the applicant. This action would result in your submission being removed from the provisions of both the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and PRIA. Any subsequent re-submission relating to the application must be submitted as a new PRIA application and subject to a fee.

The following data must be submitted.

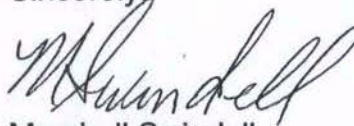
1. The efficacy data was not acceptable to support the use when used in conjunction with the four part Sterilization System, as a sterilant against *Bacillus subtilis* and *Clostridium sporogenes*. No confirmatory data were provided and all studies must be conducted under GLP.
2. The Product chemistry Data was deficient. The data must be conducted in accordance with Guidelines Series 820, Group "A" and "B" and submitted to the Agency and found acceptable to support the proposed registration.
3. These deficiencies must be corrected before the Agency can proceed further with application. Please include your proposed re-negotiated due date for this PRIA action with an explanation as to how you will resolve the deficiencies by August 20, 2007.

You have the following two options.

1. Resolve the issue(s). You may resolve the issue(s) identified in this letter by submitting, via facsimile or email, the information/data by 11/1/07, or an explanation of why it will take longer to correct the deficiencies. Please include your proposed re-negotiated PRIA due date and the date you expect to submit the fix (new data) at this time. Your re-negotiated PRIA due date must include the date that you expect to submit the fix plus an additional 10 days for in-processing of new data and 90-days for Agency review. If no other issues arise as a result of your response to this letter, and the data is found to be acceptable, it is the Agency's expectation that resolution of the deficiencies will result in the granting of your application.
2. Do nothing. If you do not respond to this letter by 11/1/07, or if you do not wish to re-negotiate the PRIA deadline, the Agency will issue a determination not to grant your application. A determination not to grant your application would remove your application from the provisions of PRIA. Subsequent re-submissions after 75 days from the date of this letter would require a new PRIA application and fee. Because this determination is not a denial under section 30(6) of FIFRA, you may request that EPA issue a formal denial under procedures outlined in section 30(6) of FIFRA and 40 CFR 152.118. The process includes publication of a notice of denial in the Federal Register and a possible public hearing. If the request for a formal denial is not received 75 days from the date of this letter, the Agency will administratively withdraw the submission pursuant to 40 CFR 152.105.

If you have questions concerning this letter, please contact me by telephone 703-308-6341 or by e-mail at Swindell.Marshall@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Marshall Swindell", written in a cursive style.

Marshall Swindell
Product Manager 33
Regulatory Management Branch1
Antimicrobials Division (7510P)

Eliot Harrison

From: Edwards.Dennis@epamail.epa.gov
Sent: Tuesday, June 19, 2007 1:00 PM
To: Eliot Harrison
Cc: Swindell.Marshall@epamail.epa.gov; Blackburn.Tajah@epamail.epa.gov
Subject: Re: FW: Sterrad Hydrogen Peroxide, 71871-G

Eliot,

The previous studies will satisfy the confirmatory efficacy requirement for this product.

Dennis Edwards
Antimicrobials Division
703-308-8087

"Eliot Harrison"
<eharrison@lewis
harrison.com>

06/13/2007 02:27
PM

Marshall
Swindell/DC/USEPA/US@EPA, Dennis
Edwards/DC/USEPA/US@EPA

To

cc

Subject
FW: Sterrad Hydrogen Peroxide,
71871-G

Marshall,
The ASP folks will let me know tomorrow regarding the scheduling of the additional efficacy studies (2 or 3 lots, depending on whether a confirmatory is required). I should have the comparison chart by the end of the week, which I will forward along with the GLP deficiency issue.

Eliot

-----Original Message-----

From: Eliot Harrison
Sent: Tuesday, May 22, 2007 12:10 PM
To: 'swindell.marshall@epa.gov'; 'edwards.dennis@epa.gov'
Subject: Sterrad Hydrogen Peroxide, 71871-G

Dennis,

As a follow-up to our meeting last week, below is my understanding of the additional data/information that ASP will have to provide for the above product:

1) Sterilant efficacy data for 2 additional lots of the product. This study will be conducted in accordance with GLP standards using the AOAC Sporicidal protocol.

2) Additional information on the two GLP deficiencies that were noted on the GLP Compliance page. These deficiencies are as follows: "Data for Maintenance of Cultures was not recorded in compliance with GLP requirements" and "Data for Propagation and Harvesting of Bacterial Cultures were Not Recorded Promptly as per GLP"

3) A comparison chart of the different ASP sterilizer units and a justification that the "100S" unit is "worst-case" for efficacy testing.

The Agency will let ASP know if the confirmatory efficacy study can be satisfied by the previously submitted efficacy studies provided by ASP or whether a confirmatory is required. If a confirmatory is required, the study can be conducted at the same lab as long as there is a different study director.

Finally, can you check with Juan Negron on the outstanding chemistry issues. If additional data is needed, we need to know ASAP so these can be submitted with the efficacy data.

Let me know if I missed anything.

Eliot

Eliot Harrison

From: Eliot Harrison
Sent: Monday, May 14, 2007 8:25 PM
To: 'swindell.marshall@epa.gov'
Subject: FW: Sterrad Hydrogen Peroxide, File Symbol No. 71871-G

Hi Marshall,
 If available, can you arrange to have a projector for the meeting on Wednesday.
 Thanks,
 Eliot

-----Original Message-----

From: Eliot Harrison
Sent: Sunday, May 06, 2007 6:57 PM
To: 'swindell.marshall@epa.gov'
Subject: FW: Sterrad Hydrogen Peroxide, File Symbol No. 71871-G

Hi Marshall,
 Background information for the meeting on May 16th from 10-11.
 Eliot

-----Original Message-----

From: Eliot Harrison
Sent: Tuesday, April 24, 2007 7:18 PM
To: 'swindell.marshall@epa.gov'
Subject: FW: Sterrad Hydrogen Peroxide, File Symbol No. 71871-G

Marshall,
 As per our discussion earlier. Can we set something up for next week since the ASP person who needs to attend is in DC next week.
 Eliot

-----Original Message-----

From: Eliot Harrison
Sent: Friday, April 06, 2007 5:10 PM
To: 'swindell.marshall@epa.gov'
Cc: 'edwards.dennis@epa.gov'; 'terry.martha@epa.gov'
Subject: Sterrad Hydrogen Peroxide, File Symbol No. 71871-G

Marshall,

In response to the Agency's letter dated March 22, 2007 and the accompanying product chemistry and efficacy reviews, please note:

1. I believe that all the requisite product chemistry data has previously been submitted previously to the Agency. It appears that the chemistry reviewer might not have been aware of the prior submission. Please refer to the attached documents.

2. We need to have a meeting to discuss the outstanding efficacy issues prior to the conduct of any additional studies. As you know, ASP has submitted six (6) separate, full AOAC studies on Sterrad Hydrogen Peroxide. These studies were conducted with the various commercially available sterilizers that can use Sterrad Hydrogen Peroxide. All of these studies passed so there hasn't been any issue regarding the effectiveness of the product. Moreover, all of the sterilizers have successfully gone through FDA's 510(k) process in the past 5-7 years.

In reviewing sterilant registrations for other vaporized hydrogen peroxide products and for ethylene oxide, it appears that demonstrating efficacy on the product, as is, will suffice. Therefore, we would like to discuss how additional studies will be conducted so they will be considered acceptable by the Agency. Otherwise (if

studies had to be conducted in the sterilizer machines), we would be faced with conducting at least 9 additional, separate studies. The proposed agenda for the meeting is below. If possible, we would like to meet on either: Monday April 23 (afternoon only), April 30, May 1, 2, 3 or 4.

Agenda

1. Description of Sterrad Hydrogen Peroxide and How it Is Used.
2. Summary of Previously Conducted Studies
3. Proposed studies to register the product.

Regards,
Eliot

-----Original Message-----

From: office

Sent: Friday, April 06, 2007 4:52 PM

To: Eliot Harrison


Subject:

Product Chemistry Issues

The data deficiencies mentioned on pages 6 and 7 of the product chemistry review were mostly all addressed in the original (2002) submission of Sterrad Hydrogen Peroxide. Refer to the attached data matrix and chart below.

Data Requirement	Submission I.D.
Product Identity	45680801
Description of Materials	45680801
Formulation Process	45680801
Formulation of Impurities	45680801
Certified Limits	45680801
Analytical Method	45680801
Color	45680802
Physical State	45680802
Odor	45680802
Oxidation/reduction	45680802
Flammability	46992801
Explosibility	45680802
Storage Stability	45680805
Miscibility	Not applicable - not diluted with petroleum solvents
Corrosion Characteristics	46992801
Dielectric breakdown voltage	Not applicable - not used around electrical equipment
pH	45680804
Viscosity	45680802
Density	45680803

**Recommendation of Division Directors
Negotiated Due Dates**

Decision#: 372392	Registration#: 71871-G	Petition #: N/A
Fee Category: A-54	PRIA Decision Time Frame: 120 days	
Submitted by: Martha Terry	Branch: RMBI	Date: 06/28/07
Company: Advanced Sterilization Products		
Original Due Date: 04/10/07	Proposed New Due Date: 02/01/08	
Previous Negotiated Due Dates: 10/11/07		
Is the "Fix" in-house? No	If not, date "Fix" expected: 10/1/07	
Issue (describe in detail): The efficacy data was not acceptable to support the use when used in conjunction with the four part Sterilization System, as a sterilant against <i>Bacillus subtilis</i> and <i>Clostridium sporogenes</i> . No confirmatory data were provided and all studies must be conducted under GLP. The company has major deficiencies regarding the proposed label claims as in regard to the four Sterilization System User's guide. The company must submit new efficacy data and labels. The product chemistry data was deficient. The company has to submit the 830 guidelines Group "A" and "B".		
Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates): The company has requested an time extension of 150 days from 10/1/07 to 02/01/08 including a "fix" date of 10/01/07. This time will allow the company time to generate the data and correct the deficiencies on the label.		
Rationale for Proposed Due Date: The company determined it needed additional time to conduct the needed efficacy studies.		
Other Comments/Deficiency Type: Product Chemistry: <input checked="" type="checkbox"/> Acute Tox: <input type="checkbox"/> Efficacy: <input checked="" type="checkbox"/> Labeling: <input type="checkbox"/> Other: <input type="checkbox"/>		
"75 Day" Letter appropriate? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Why Not?		
Registrant notified that this is the last negotiation? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Why Not?		
Approve: <input checked="" type="checkbox"/>	Disapprove: <input type="checkbox"/>	
If disapproved, action to be taken:		
OD or DOD Signature: 	Date: 6-28-07	

Martha Terry/DC/USEPA/US
06/19/2007 03:48 PM

To Marshall Swindell/DC/USEPA/US@EPA, Dennis
Edwards/DC/USEPA/US@EPA
cc
bcc

Subject Fw: Sterrad Hydrogen Peroxide (EPA File Symbol 71871-G)

----- Forwarded by Martha Terry/DC/USEPA/US on 06/19/2007 03:49 PM -----



"Eliot Harrison"
<eharrison@lewisharrison.co
m>
06/19/2007 03:43 PM

To Martha Terry/DC/USEPA/US@EPA
cc
Subject FW: Sterrad Hydrogen Peroxide (EPA File Symbol 71871-G)

Hi Martha,

ASP is requesting that the PRIA due date for Sterrad Hydrogen Peroxide, File Symbol No. 71871-G be extended until February 1, 2008. The additional time is needed in order to conduct the follow-up sterilant efficacy studies and for the Agency to review these studies. The studies will be initiated by August 1 and should be ready for submission by September 15, 2007. In order to account for any delays in the conduct of the studies, ASP commits to submitting the studies by October 1, 2007. The time from October 1, 2007 until February 1, 2008 is for the Agency to review the studies and make a decision on the application.

Eliot

-----Original Message-----

From: Eliot Harrison
Sent: Thursday, April 05, 2007 12:26 PM
To: 'terry.martha@epa.gov'
Subject: FW: Sterrad Hydrogen Peroxide (EPA File Symbol 71871-G)

-----Original Message-----

From: Eliot Harrison
Sent: Thursday, April 05, 2007 11:47 AM
To: 'terry.martha@epa.gov'
Cc: 'swindell.marshall1@epa.gov'
Subject: FW: Sterrad Hydrogen Peroxide (EPA File Symbol 71871-G)

Hi Martha,

Thank you for your voice mail regarding the registration for Sterrad Hydrogen Peroxide (EPA File Symbol 71871-G). Please note that we will be submitting a response to the Agency's letter of 3/22/07 by Thursday.

Regarding renegotiation of the PRIA due date, we'd like to request the Agency to extend this due date to October 11, 2007. In addition, we

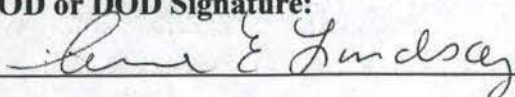
will submit any additional product chemistry and/or efficacy data that is needed to complete the review of the application by June 20, 2007.

Feel free to give me a call or send me an e-mail if you have any questions or if I can be of further assistance.

Best regards,

Ana Rodriguez-Koster
Lewis & Harrison, LLC
Home office phone#: 410-579-5848
Office phone#: 202-393-3903 x.17
f. 202-393-3906
alkoster@lewisharrison.com

**Recommendation of Division Directors
Negotiated Due Dates**

Decision#: 372392	Registration#: 71871-G	Petition #: N/A
Fee Category: A-54	PRIA Decision Time Frame: 120 days	
Submitted by: Martha Terry	Branch: RMBI	Date: 04/06/07
Company: Advanced Sterilization Products		
Original Due Date: 04/10/07	Proposed New Due Date: 10/11/07	
Previous Negotiated Due Dates: None		
Is the "Fix" in-house? No	If not, date "Fix" expected: 06/20/07	
Issue (describe in detail): <p>The efficacy data was not acceptable to support the use of the product as a sterilant. No confirmatory data were provided. The company has major deficiencies regarding the proposed label claims. The product chemistry data were also deficient. New efficacy and chemistry data must be provided as well as a new label.</p>		
Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates): <p>This is the first negotiation for this registration application. The company has requested a time extension of 180 days from 04/10/07 to 10/11/07. This time frame will allow the company to conduct the necessary studies as well as allow the Agency time to review the data.</p>		
Rationale for Proposed Due Date: Additional time is needed for the company to provide the required data. Built into the time extension request is time to allow the Agency to review the studies.		
Other Comments/Deficiency Type: Product Chemistry: <input checked="" type="checkbox"/> Acute Tox: <input type="checkbox"/> Efficacy: <input checked="" type="checkbox"/> Labeling: <input checked="" type="checkbox"/> Other: <input type="checkbox"/>		
Approve:	Disapprove:	
If disapproved, action to be taken:		
OD or DOD Signature: 		Date: 4-06-07

Martha Terry/DC/USEPA/US
04/05/2007 12:28 PM

To Dennis Edwards/DC/USEPA/US@EPA
cc Marshall Swindell/DC/USEPA/US@EPA
bcc
Subject Fw: Sterrad Hydrogen Peroxide (EPA File Symbol 71871-G)

Hi Dennis,

Updated copy.

----- Forwarded by Martha Terry/DC/USEPA/US on 04/05/2007 12:28 PM -----



"Eliot Harrison"
<eharrison@lewisharrison.co
m>
04/05/2007 12:25 PM

To Martha Terry/DC/USEPA/US@EPA
cc
Subject FW: Sterrad Hydrogen Peroxide (EPA File Symbol 71871-G)

-----Original Message-----

From: Eliot Harrison
Sent: Thursday, April 05, 2007 11:47 AM
To: 'terry.martha@epa.gov'
Cc: 'swindell.marshall1@epa.gov'
Subject: FW: Sterrad Hydrogen Peroxide (EPA File Symbol 71871-G)

Hi Martha,

Thank you for your voice mail regarding the registration for Sterrad Hydrogen Peroxide (EPA File Symbol 71871-G). Please note that we will be submitting a response to the Agency's letter of 3/22/07 by Thursday.

Regarding renegotiation of the PRIA due date, we'd like to request the Agency to extend this due date to October 11, 2007. In addition, we will submit any additional product chemistry and/or efficacy data that is needed to complete the review of the application by June 20, 2007.

Feel free to give me a call or send me an e-mail if you have any questions or if I can be of further assistance.

Best regards,

Ana Rodriguez-Koster
Lewis & Harrison, LLC
Home office phone#: 410-579-5848
Office phone#: 202-393-3903 x.17
f. 202-393-3906
alkoster@lewisharrison.com

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 22 2007



Office of Pesticide Programs

**Advanced Sterilization Products
33 Technology Drive
Irvine, CA 92618**

**AGENT: Lewis & Harrison
122 C Street, N. W., Suite 740
Washington, D. C. 20001**

Attention: Ana Rodriguez-Koster

**Subject: Sterrad Hydrogen Peroxide
EPA File Symbol No. 71871-G
Application Dated November 2, 2006**

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is not acceptable. The proposed product is deficient must be corrected before the review process can be initiated.

Our records indicate that the decision review period for EPA to make a determination pursuant to the Pesticide Registration Improvement Act (PRIA) regarding the above referenced application ends on April 11, 2007. The Agency has reviewed the data associated with this application in accordance with PR Notice 86-5. The data was found to be unacceptable in accordance with the deficiencies outlined below:

1. EFFICACY DATA

In response to the original submission dated 5/1/02) and re-submission (dated 8/15/02), the Agency's letter stated that "the submitted efficacy studies under MRID 456808-06 thru 456808-08 were not acceptable. They do not support the use of the product, STERRAD hydrogen Peroxide, as a sterilizer when tested using the STERRAD 50 Sterilization System, the STERRAD 100S Sterilization System, and the STERRAD 200 Sterilization System for a 'full cycle', implying that other (briefer/less stringent) cycle options were available to system users. The data package submitted in response to an

EPA letter (dated December 20, 2002) is a resubmission of the original application. The efficacy data under MRID Nos 469928-02 thru 469928-04) an addendum to the study assigned MRID No. 469928-02, are not acceptable. Please refer to the enclosed copy of the Efficacy Review under "CONCLUSIONS" and "RECOMMENDATIONS" for further deficiencies and comments.

2. PRODUCT CHEMISTRY DATA

The Product Chemistry Data was found to be unacceptable. You must submit a complete package of the 830 Guidelines Group "A & B". Refer to the enclosed copy of the Product Chemistry Review under "FINDINGS", "RECOMMENDATIONS" and "CONCLUSIONS" for further deficiencies and comments.

Thus, the Agency, in meeting its obligation to make a determination within the PRIA decision review period and based upon the information currently before it, has determined that your application does not meet the standard for registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and, therefore, cannot be granted at this time.

Although this concludes EPA's PRIA review of your application, this determination is not a denial of your application pursuant to section 3(c)(6) of FIFRA. Pursuant to 40 CFR § 152.105, you have 75 days to address the deficiencies or notify the Agency when the information will be submitted to address the deficiencies.

You have the following three options.

1. Resolve the issues within 10 business days. You may resolve the issues identified in this letter by submitting, via facsimile or email, the information/data requested within 10 business days from date of this letter. Please include your proposed re-negotiated due date for this PRIA action at that time.
2. Resolve the issues after 10 business days. If you are not able to correct the issues within 10 business days, please include an explanation of why it will take longer to submit correct deficiencies. Please include your proposed re-negotiated due date for this PRIA action at that time.

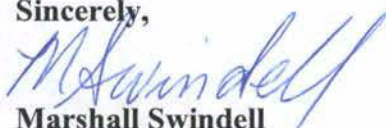
Page 3

EPA File Symbol No. 71871-G

3. Do nothing. If you do not respond to this letter, the Agency will administratively withdraw your application on June 27, 2007. Once the application is administratively withdrawn, you will need to submit a new application to the Agency and will be subject to a new PRIA fee.

If you have questions concerning this letter, please contact me by telephone at 703-308-6341 or by e-mail at Swindell.Marshall@epa.gov or Martha Terry by telephone at (703) 308-6217 or by email at Terry.Martha@epa.gov.

Sincerely,

A handwritten signature in blue ink, appearing to read "M. Swindell", is written over the typed name.

Marshall Swindell

Product manager-33

Regulatory Management Branch I
Antimicrobials Division (7510P)

Enclosures

DATA PACKAGE BEAN SHEET

Date: 09-Jan-2007

Page 1 of 1

Decision #: 372392

DP #: (335345)

*** Registration Information ***

Registration: 71871-G - STERRAD HYDROGEN PEROXIDE

Company: 71871 - ADVANCED STERILIZATION PRODUCTS

Risk Manager: RM 33 - Marshall Swindell - (703) 308-6341 Room# PY1 S-8828

Risk Manager Reviewer: Martha Terry MTERRY

Sent Date: _____

Calculated Due Date: 11-Apr-2007

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

PM Reviewer → 03/12/07 ✓

Action Desc: (A54) NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM) USES;

Ingredients: 000595, Hydrogen peroxide(59%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 09-Jan-2007

Due Back: _____

DP Ingredient: 000595, Hydrogen peroxide

DP Title: PRODUCT CHEMISTRY DATA PACKAGE

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: AD / PSB

1/10/07

Last Possible Science Due Date: 12-Mar-2007

Team Name: CHEM

1/10/07

Science Due Date: 11-Mar-2007

Reviewer Name: Juan

1/10/07

2/22/07

Sub Data Package Due Date: 4/10/07

Contractor Name: _____

*** Studies Sent for Review ***

No Studies

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

PLEASE REVIEW THE PRODUCT CHEMISTRY DATA PACKAGE IN SUPPORT OF THE PENDING PRODUCT. ATTACHED IS THE LABEL AND CSF. THANKS

PRIA A-54 SUBMISSION #801691 SCI DUE DATE 3/11/07 ADMIN DUE 4/11/07

STERRAD®

**HYDROGEN PEROXIDE
AQUEOUS SOLUTION STERILANT**

**FOR USE IN THE STERILIZATION OF
LABORATORY AND INDUSTRIAL EQUIPMENT**

**KEEP OUT OF REACH OF CHILDREN
DANGER**

See Side Panel For Additional Precautionary Statements

STATEMENT OF PRACTICAL TREATMENT

If In Eyes: Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

If On Skin or Clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes.

If Swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

If Inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment. You may also contact 1-800-xxxx-xxxx for emergency medical treatment information.

Note To Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

ACTIVE INGREDIENT: Hydrogen peroxide 59.0%
INERT INGREDIENTS: 41.0%
TOTAL: 100.0%

EPA Registration No.: 71871-_____
EPA Establishment No.: _____

2

Net Contents: _____

LOT: _____

PRECAUTIONARY STATEMENTS

DANGER. CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Do not breathe vapor or spray mist. Wear protective eyewear (goggles, face shield or safety glasses) and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash clothing before reuse.

PHYSICAL AND CHEMICAL HAZARDS.

Hydrogen peroxide is a strong oxidizing agent and poses a hazard for fire, explosion or container rupture. Avoid contact with contamination or combustible materials. Do not use or store near heat or open flame. Shoes clothing, or other combustible materials that have come into contact with hydrogen peroxide must be immediately and thoroughly rinsed with water to avoid potential fire hazards. In case of fire, use only water. Contain spills and dilute with 20 parts of water. After diluting the contained spill, use sodium metabisulfide or sodium sulfite (1.9 lbs. SO₂ equivalent per 500 mL of spilled material) may be used to deactivate the hydrogen peroxide.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to birds, mammals, fish and aquatic invertebrates. Do not charge effluent containing this product into lakes, streams, ponds, estuaries oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System and the permitting authority has been notified in writing prior to discharge. Do not discharge this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Manufactured by:

ASP ADVANCED STERILIZATION PRODUCTS®

a Johnson & Johnson company
Division of Ethicon, Inc.



33 Technology Drive, Irvine, CA 92618-9824
(888) STERRAD

Authorized EC Representative
Ethicon GmbH
Poststraße 1, D-22844 Norderstedt

©ASP, 2000

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

STERRAD® Hydrogen Peroxide is intended for sterilizing:

- tissue culture equipment and materials
- laboratory equipment (including glassware) and instrumentation
- medical instruments and devices in veterinary facilities

STERRAD® Hydrogen Peroxide may be used for treating items made of aluminum, brass, Delrin, ethyl vinyl acetate (EVA), glass, Kraton, latex, neoprene, nylon, Monel, polycarbonate, polyethylene, polystyrene, polypropylene, polyurethane, polyvinyl chloride (PVC), silicone, stainless steel, Teflon/polytetrafluoroethylene (PTFE)

For Use In The STERRAD® 200 Sterilizer Only.

Two (2) Cycles/Cassette

- Each cell contains not less than 0.0868 oz. (0.898 ± 0.003 oz.) [2466 mg (2550 ± 84 mg)] of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
- If the yellow indicator has turned red, the cassette might have been damaged. Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise:
- Remove plastic wrap from cassette sleeve. Do not remove cassette from the remaining cardboard packaging.
- Orient the arrow so that it is on top of the cassette sleeve and pointing away from you.
- Insert the cassette sleeve into the STERRAD® 200 Sterilizer.
- Push the cassette sleeve completely into the injector. Once properly positioned, the cassette will automatically be accepted and positioned for use by the Sterilizer. The monitor will read "Cassette Accepted." If the cassette is not accepted because the barcode cannot be read or the cassette has expired, the monitor will read "Please Remove Cassette." Should this occur, please insert a new cassette.
- When the cassette is empty or has reached its labeled expiration date, or has been in the machine 8 days (due to the higher temperature in the machine), it will automatically be re-inserted into the packaging and the monitor will display "Remove Cassette." Grasp and remove the sleeve containing the empty cassette. The chemical indicator on the cassette sleeve may have turned red due to the higher temperature in the machine.
- Discard the sleeves containing the empty cassettes as indicated in the disposal directions.
- If an UNUSED cassette extends or falls out of the sleeve, wear gloves to replace the cassette in the original sleeve and call ASP Customer Service.
- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® 200 Sterilizer cycle time is approximately 75 minutes.
- **Refer to STERRAD® 200 Sterilizer Operator's Guide for additional information.**

- OR -

For Use In The STERRAD® NX Sterilizer Only.

Five (5) Cycles/Cassette

- Each cell contains not less than 1850 ± 50 µ of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
- If the yellow indicator has turned red, the cassette might have been damaged. Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise:
- Remove plastic wrap from cassette sleeve. Do not remove cassette from the remaining cardboard packaging.
- Orient the arrow so that it is on top of the cassette sleeve and pointing away from you.
- Insert the cassette sleeve into the STERRAD® NX Sterilizer.
- Push the cassette sleeve completely into the injector. Once properly positioned, the cassette will automatically be accepted and positioned for use by the Sterilizer. The monitor will read "Cassette Accepted." If the cassette is not accepted because the barcode cannot be read or the cassette has expired, the monitor will read "Please Remove Cassette." Should this occur, please insert a new cassette.
- When the cassette is empty or has reached its labeled expiration date, or has been in the machine 8 days (due to the higher temperature in the machine), it will automatically be re-inserted into the packaging and the monitor will display "Remove Cassette." Grasp and remove the sleeve containing the empty cassette. The chemical indicator on the cassette sleeve may have turned red due to the higher temperature in the machine.
- Discard the sleeves containing the empty cassettes as indicated in the disposal directions.
- If an UNUSED cassette extends or falls out of the sleeve, wear gloves to replace the cassette in the original sleeve and call ASP Customer Service.

- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® NX Sterilizer has two cycle times: the 28-minute Standard cycle is for most surgical instruments and the 38-minute Advance cycle is for the flexible endoscope.
- **Refer to STERRAD® NX Sterilizer Operator's Guide for additional information.**

- OR -

For Use In The STERRAD® 50 Sterilizer Only.

Five (5) Cycles/Cassette

- Each cell contains not less than 0.592 fl. oz. (0.609 ± 0.017 fl. oz.) [(1750 µL (1800µL ± 50µL))] of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
- If the yellow indicator has turned red, the cassette might have been damaged. Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise:
- Remove plastic wrap from cassette sleeve. Do not remove cassette from the remaining cardboard packaging.
- Orient the arrow so that it is on top of the cassette sleeve and pointing away from you.
- Insert the cassette sleeve into the STERRAD® 50 Sterilizer.
- Push the cassette sleeve completely into the injector. Once properly positioned, the cassette will automatically be accepted and positioned for use by the Sterilizer. The monitor will read "Cassette Accepted." If the cassette is not accepted because the barcode cannot be read or the cassette has expired, the monitor will read "Please Remove Cassette." Should this occur, please insert a new cassette.
- When the cassette is empty or has reached its labeled expiration date, or has been in the machine 10 days (due to the higher temperature in the machine), it will automatically be re-inserted into the packaging and the monitor will display "Remove Cassette." Grasp and remove the sleeve containing the empty cassette. The chemical indicator on the cassette sleeve may have turned red due to the higher temperature in the machine.
- Discard the sleeves containing the empty cassettes as indicated in the disposal directions.
- If an UNUSED cassette extends or falls out of the sleeve, wear gloves to replace the cassette in the original sleeve and call ASP Customer Service.
- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® 50 Sterilizer cycle time is approximately 45 minutes.
- **Refer to STERRAD® 50 Sterilizer Operator's Guide for additional information.**

- OR -

For Use In The STERRAD® 100S Sterilizer Only.

Five (5) Cycles/Cassette

- Each cell contains not less than 0.592 fl. oz. (0.609 ± 0.017 fl. oz.) [(1750 µL (1800µL ± 50µL))] of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
- If the yellow indicator has turned red, the cassette might have been damaged. Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise:
- Remove plastic wrap
- Remove cassette from box.
- Insert the cassette sleeve into the STERRAD® 100S Sterilizer.
- The cassette will be accepted automatically.
- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® 100S Sterilizer cycle time is approximately 55 minutes.
- **Refer to STERRAD® 100S Sterilizer Operator's Manual for additional information.**

This product is not to be used as a terminal sterilant / high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: Store upright at all times. Keep product in its original packaging at a controlled room temperature, between 15° - 30°C (59° - 86°F). Do not expose product to direct sunlight, radiant heat, powdered metals, powdered metals, cyanide, hexavalent chromium compounds, other oxidizers, reducers, combustible materials or flammable vapors.

PESTICIDE DISPOSAL: Bottles: If bottle contains less than 50 mL, empty contents into sink with running water according to local regulatory agency requirements or dispose as hazardous waste. **Bottles and Cassettes:** Hydrogen peroxide is classified as a DOT oxidizer and a hazardous waste under US EPA hazardous waste regulation and it is a violation of Federal law to improperly dispose of pesticides. If these wastes cannot be disposed of by use or according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Cassettes: Discard empty container per hospital policy. **Bottles:** Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

DATA PACKAGE BEAN SHEET

Date: 20-Mar-2007

Page 1 of 3

Decision #: 372392

DP #: (335346)

PRIA

Parent DP#:

*** Registration Information ***

Registration: 71871-G - STERRAD HYDROGEN PEROXIDE

Company: 71871 - ADVANCED STERILIZATION PRODUCTS

Risk Manager: RM 33 - Marshall Swindell - (703) 308-6341 Room# PY1 S-8828

Risk Manager Reviewer: Martha Terry MTERRY

Sent Date: _____

Calculated Due Date: 11-Apr-2007

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A54) NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM) USES;

Ingredients: 000595, Hydrogen peroxide(59%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 09-Jan-2007

Due Back: _____

DP Ingredient: 000595, Hydrogen peroxide

DP Title: EFFICACY DATA PACKAGE

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

	<u>Date In</u>	<u>Date Out</u>	
Organization: <u>AD / PSB</u>	<u>10-Jan-2007</u>	_____	Last Possible Science Due Date: <u>12-Mar-2007</u>
Team Name: <u>EET</u>	<u>10-Jan-2007</u>	_____	Science Due Date: <u>26-Mar-2007</u>
Reviewer Name: <u>Blackburn, Tajah</u>	<u>15-Mar-2007</u>	<u>20-Mar-2007</u>	Sub Data Package Due Date: <u>10-Apr-2007</u>
Contractor Name: <u>DynCorp</u>	<u>24-Jan-2007</u>	<u>13-Mar-2007</u>	

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Printed on Page 3

*** Data Package Instructions ***

PLEASE REVIEW THE EFFICACY DATA (MRID # 569928-02, -03, -04, AND -05) IN SUPPORT OF THE PENDING PRODUCT. ATTACHED IS THE LABEL AND CSF. THANKS

PRIA A-54 SUBMISSION #801691 SCI DUE 3/11/07 ADMIN DUE 4/11/07



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

March 19, 2007

MEMORANDUM

Subject: Efficacy Review for EPA Reg. No. 71871-G, STERRAD Hydrogen Peroxide Aqueous Solution Sterilant; DP Barcode: 335346

From: Tajah L. Blackburn, Ph.D., Microbiologist
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P) *[Signature]*

Thru: Michele Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

To: Marshall Swindell PM 32/ Martha Terry
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Advanced Sterilization Products
33 Technology Drive
Irvine, CA 92618-9824

Formulations from Label

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Hydrogen Peroxide.....	59.0%
<u>Inert Ingredients</u>	41.0%
Total	100.0%

I BACKGROUND

The product, STERRAD Hydrogen Peroxide (EPA File Symbol 71871-G), is a new product. The applicant requested to register the product as a sterilant of laboratory and industrial equipment. The product is to be used in conjunction with one of four sterilization systems. All studies were conducted at Advanced Sterilization Products, located at 33 Technology Drive in Irvine, CA 92618.

The data package is a resubmission of the original application, prepared in response to an EPA letter (dated December 20, 2002). The data package contained a letter from the applicant's representative (dated November 2, 2006), EPA Form 8570-4 (Confidential Statement of Formula), three studies (MRID Nos. 469928-02 through 469928-04), an addendum to the study assigned MRID No. 469928-02 (dated January 25, 2007), Statements of No Data Confidentiality Claims for all three studies, and the proposed label. The data package also contained user's guides to the STERRAD 50 Sterilization System, STERRAD 100S Sterilization System, STERRAD 200 Sterilization System, and the STERRAD NX Sterilization System.

Note: The product, STERRAD Hydrogen Peroxide, is a simple [REDACTED]

Note: EPA Form 8570-4 (Confidential Statement of Formula) contains Confidential Business Information. Confidential data or information contained on EPA Form 8570-4 has not been included in this report.

Note: In response to the original submission (dated 5/1/02) and re-submission (dated 8/15/02), the Agency's letter stated that "the submitted efficacy data (MRID Nos. 456808-06 through -08) are not acceptable. They do not support the use of the product, STERRAD Hydrogen Peroxide, as a sterilizer when tested using the STERRAD 50 Sterilization System, the STERRAD 100S Sterilization System, and the STERRAD 200 Sterilization System for a 'full cycle' (i.e., approximately 30 minutes). Each study was performed at the 'full cycle,' implying that other (briefed/less stringent) cycle options were available to system users. Although no survival was observed on either the suture or penicylinder carriers, the applicant to include the required three lots of product in each study. A 60-day old product lot was used in at least one study (i.e., MRID No. 456808-07). The required number and type of carriers were used per lot of product. Bacteriostasis controls showed survival. The applicant's own laboratory performed each of the tests, and stated that the studies were not performed in accordance with GLPs. Although the lab felt that the GLP deviations were not serious, the report does not state what the violations were. No efficacy data were submitted using the product, STERRAD Hydrogen Peroxide, with the STERRAD 800 Sterilization System. The efficacy data submitted for the product using STERRAD 50, STERRAD 100S, and the STERRAD 200 were inadequate for the following reasons:

- a. The studies were not performed according to GLPs.
- b. Only one lot was tested in each study, instead of the required three lots (one of which is to be greater than 60 days old at the time of testing); and ,
- c. No contact time/processing time was indicated on the label, and the efficacy testing apparently relied on the 'best case'.

- d. The product label should state the required length of exposure, or treatment, for each of the sterilization systems."

II USE DIRECTIONS

The product is designed to be used for sterilizing tissue culture equipment and materials; laboratory equipment (including glassware) and instrumentation; and medical instruments and devices in veterinary facilities. The product may be used for treating items made of aluminum, brass, Delrin, ethyl vinyl acetate, glass, Kraton, latex, neoprene, nylon, Monel, polycarbonate, polyethylene, polystyrene, polypropylene, polyurethane, polyvinyl chloride, silicone, stainless steel, and Teflon/polytetrafluoroethylene. Directions on the proposed label provided the following information regarding use of the product as a sterilant:

For Use in the STERRAD 50 Sterilizer:

Five (5) Cycles/Cassette. Each cassette contains not less than 0.592 fluid ounces of the product. Inspect the cassette for indications of damage. If no damage is indicated, remove the cassette from the plastic wrap; do not remove the cassette from the cardboard packaging. Place the cassette so that the arrow is on top of the cassette and pointing away from the user. Insert the cassette into the STERRAD 50 Sterilizer. Push the cassette into the machine. If properly positioned, the monitor will read "Cassette Accepted." If the cassette is not acceptable, the monitor will read "Please Remove Cassette." Discard the cassette and the cassette sleeve according to the disposal directions. The STERRAD 50 Sterilizer cycle time is approximately 45 minutes. Refer to the STERRAD 50 Sterilizer Operator's Guide for additional information.

For Use in the STERRAD 100S Sterilizer:

Five (5) Cycles/Cassette. Each cassette contains not less than 0.592 fluid ounces of the product. Inspect the cassette for indications of damage. If not damage is indicated, remove the cassette from the plastic wrap and the box. Insert the cassette into the STERRAD 110S Sterilizer. The cassette will be accepted automatically. The STERRAD 100S Sterilizer cycle time is approximately 55 minutes. Refer to the STERRAD 100S Sterilizer Operator's Manual for additional information.

For Use in the STERRAD 200 Sterilizer:

Two (2) Cycles/Cassette. Each cassette contains not less than 0.0868 ounces of the product. Inspect the cassette for indications of damage. If no damage is indicated, remove the cassette from the plastic wrap; do not remove the cassette from the cardboard packaging. Place the cassette so that the arrow is on top of the cassette and pointing away from the user. Insert the cassette into the STERRAD 200 Sterilizer. Push the cassette into the machine. If properly positioned, the monitor will read "Cassette Accepted." If the cassette is not acceptable, the monitor will read "Please Remove Cassette." Discard the cassette and the cassette sleeve according to the disposal directions. The

STERRAD 200 Sterilizer cycle time is approximately 75 minutes. Refer to the STERRAD 200 Sterilizer Operator's Guide for additional information.

For Use in the STERRAD NX Sterilizer:

Five (5) Cycles/Cassette. Each cassette contains not less than $1850 \pm 50 \mu(?)$ of the product. Inspect the cassette for indications of damage. If no damage is indicated, remove the cassette from the plastic wrap; do not remove the cassette from the cardboard packaging. Place the cassette so that the arrow is on top of the cassette and pointing away from the user. Insert the cassette into the STERRAD NX Sterilizer. Push the cassette into the machine. If properly positioned, the monitor will read "Cassette Accepted." If the cassette is not acceptable, the monitor will read "Please Remove Cassette." Discard the cassette and the cassette sleeve according to the disposal directions. The STERRAD NX Sterilizer has two cycle times: a 28-minute standard cycle for most surgical instruments and a 38-minute advanced cycle for the flexible endoscope. Refer to the STERRAD NX Sterilizer Operator's Guide for additional information.

Note: (?) Add correct units on the proposed label.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Sterilizers

The AOAC Sporocidal Test is required for substantiating sterilizing claims. The following information applies to all products represented as sporocidal or sterilizing agents. Sixty carriers, representing each of 2 types of surfaces (porcelain penicylinders and silk suture loops), must be tested against spores of both *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584) on 3 product samples representing 3 different product lots, one of which is at least 60 days old (240 carriers per sample; a total of 720 carriers). Any sterilizing agent (liquid, vapor, or gas) that is recommended for use in a specific device must be tested by the AOAC Sporocidal Test in that specific device and according to the directions for use. Killing on all of the 720 carriers is required; no failures are permitted. Data to support sterilizing claims must be confirmed by tests conducted by a second, independent laboratory of the applicant's choice (other than the laboratory that developed the original data). The following minimal confirmatory data must be developed on one sample of the product: Thirty carriers with each of 2 types of surfaces (silk suture loops and porcelain penicylinders) against spores of both *Bacillus subtilis* and *Clostridium sporogenes* (a total of 120 carriers) by the AOAC Sporocidal Test. These Agency standards are presented in DIS/TSS-9.

IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 469928-02 "AOAC Sporicidal Activity of Disinfectants Test in the STERRAD 100S Sterilization System for EPA Registration Using STERRAD Hydrogen Peroxide," Test Organisms: *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584), by Harriet Chan-Myers. Study conducted at Advanced Sterilization Products. Study completion date – September 22, 2006. Study Number – EPA 100s.

Note: Information in an addendum to this study (dated January 25, 2007) indicates that Lot No. LA036838129-LB10014 was at least 60 days old at the time of testing.

This study was conducted against *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584). One lot (Lot No. LA036838129-LB10014) of the product, STERRAD Hydrogen Peroxide, was tested using the AOAC Sporicidal Activity of Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. The product lot was at least 60 days old at the time of testing. No organic load was used in testing. Three tests (i.e., replicates) of the single product lot were tested using the STERRAD 100S Sterilizer (PC 10101, with a manual injection system). For each test, sixty (60) porcelain penicylinder carriers and sixty (60) pre-tied polyester suture loops per microorganism were contaminated by immersion in a 72-hour old culture of the test organism, at a ratio of 1 carrier per 1 ml of broth. The carriers were vacuum-dried in a desiccator containing CaCl₂ at ≥ 25 inches Hg for 40 minutes, and then dried under vacuum for an additional 24 hours. The spores on the carriers were rehydrated by 1-hour immersion in sterile deionized water, at a ratio of 6 carriers per ≤ 20 ml water. The carriers were aseptically removed, drained for 20 minutes, and then placed in Tyvek pouches. Five carriers were placed in each pouch. The pouches containing the contaminated carriers were placed on the racks in the STERRAD 100S Sterilizer chamber. A full sterilization cycle was run using an injection volume of 1440 Φ L of the product for each half cycle. The full sterilization cycle consisted of a preconditioning with 10 minutes pre-plasma, followed by two sequential sterilization processes each with 6 minutes injection, 2 minutes diffusion, and 2 minutes post-plasma. [According to the laboratory study, 1400 μ L is the minimum cassette filled volume; a worst-case scenario.] Following completion of the sterilization cycle, each carrier was transferred to individual tubes containing Fluid Thioglycollate Medium with catalase. After subculturing, the carriers were transferred to secondary subculture tubes containing Fluid Thioglycollate Medium. The subcultures were incubated for 21 days at 35-37°C, and then examined for growth. Tubes showing no growth were heat-shocked for 20 minutes at 80°C, re-incubated for 72 hours at 35-37°C, and again examined for growth. Controls included those for sterility, carrier viability, neutralization confirmation (i.e., bacteriostatic control; non-contaminated carriers processed through the STERRAD 100S Sterilizer), and acid resistance at 2, 5, 10, and 20 minutes.

Note: The study was conducted according to GLP standards with the following exceptions: Not all raw data was recorded promptly and in compliance with GLP standards.

Note: The laboratory study identifies the ATCC number for *Clostridium sporogenes* as ATCC 3548, ATCC 3854, and ATCC 3584; the correct number is ATCC 3584.

Note: The laboratory study describes a cancelled cycle, possibly attributed to the misalignment of empty cassette cells in the reader. The carriers used in the cancelled cycle were discarded and not tested.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

2. MRID 469928-03 "AOAC Test for STERRAD NX Sterilization System in the Standard (Short) Cycle," Test Organisms: *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584), for 53% Hydrogen Peroxide by Terry Rhee. Study conducted at Advanced Sterilization Products. Study completion date – June 10, 2004. Study ID Number – RPT02400.

This study was conducted against *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584). One lot (Lot No. RT38310-0724) of the product, 53% hydrogen peroxide, was tested using the AOAC Sporicidal Activity of Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995. The product lot was at least 60 days old at the time of testing. No organic load was used in testing. Three tests (i.e., triplicates) of the single product lot were tested using the STERRAD NX Sterilizer (Product Code 10033, Prototype 9 with software version 0.8D). For each test, sixty (60) porcelain penicylinder carriers and sixty (60) polyester suture loops per microorganism were contaminated. No details were provided about carrier contamination, drying, or rehydration. The carriers were placed in Tyvek pouches. Five carriers were placed in each pouch. The pouches containing the contaminated carriers were placed on the shelves in the STERRAD NX chamber. The standard (short) nominal full cycle was run using an injection volume of 1.5 ml of the product for each half cycle. [According to the laboratory study, 1.5 ml of 53% hydrogen peroxide for each half cycle is equivalent to the minimum cassette specification plus storage and shelf-life losses.] Following completion of the sterilization cycle, each carrier was transferred to individual tubes containing Fluid Thioglycollate Medium with catalase. At the completion of the first transfer, the carriers were transferred to secondary subculture tubes containing Fluid Thioglycollate Medium. The subcultures were incubated for 21 days at 37°C, and then examined for growth. Tubes showing no growth were heat-shocked for 20 minutes at 80°C, re-incubated for 72 hours at 37°C, and again examined for growth. Controls included those for sterility (possibly) and neutralization confirmation (i.e., bacteriostasis control; non-contaminated carriers processed through the STERRAD NX Sterilizer). No information was provided regarding acid resistance testing.

Note: This study was not performed in accordance with GLP requirements. Information following the GLP compliance statement asserts that "the design, performance and study conclusions are scientifically valid and accurate," and that the Agency "should consider this study to be reliable for decision-making purposes."

Note: The lot number of the product identified in the QA Material Analysis Report in Attachment 3 of the laboratory study does not match the lot number of the product used during testing.

3. MRID 469928-04 "AOAC Test for STERRAD NX Sterilization System in the Advanced (Long) Cycle," Test Organisms: *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584), for 53% Hydrogen Peroxide by Terry Rhee. Study conducted at Advanced Sterilization Products. Study completion date – June 10, 2004. Study ID Number – RPT02397.

This study was conducted against *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584). One lot (Lot No. RT38310-0724) of the product, 53% hydrogen peroxide, was tested using the AOAC Sporocidal Activity of Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995. The product lot was at least 60 days old at the time of testing. No organic load was used in testing. Three tests (i.e., triplicates) of the single product lot were tested using the STERRAD NX Sterilizer (Product Code 10033, Prototype 9 with software version 0.8D). For each test, sixty (60) porcelain penicylinder carriers and sixty (60) polyester suture loops per microorganism were contaminated. No details were provided about carrier contamination, drying, or rehydration. The carriers were placed in Tyvek pouches. Five carriers were placed in each pouch. The pouches containing the contaminated carriers were placed on the shelves in the STERRAD NX chamber. The advanced (long) nominal full cycle was run using an injection volume of 1.5 ml of the product for each half cycle. [According to the laboratory study, 1.5 ml of 53% hydrogen peroxide for each half cycle is equivalent to the minimum cassette specification plus storage and shelf-life losses.] Following completion of the sterilization cycle, each carrier was transferred to individual tubes containing Fluid Thioglycollate Medium with catalase. At the completion of the first transfer, the carriers were transferred to secondary subculture tubes containing Fluid Thioglycollate Medium. The subcultures were incubated for 21 days at 37°C, and then examined for growth. Tubes showing no growth were heat-shocked for 20 minutes at 80°C, re-incubated for 72 hours at 37°C, and again examined for growth. Controls included those for neutralization confirmation (i.e., bacteriostasis control; non-contaminated carriers processed through the STERRAD NX Sterilizer). No information was provided regarding acid resistance testing.

Note: This study was not performed in accordance with GLP requirements. Information following the GLP compliance statement asserts that "the design, performance and study conclusions are scientifically valid and accurate," and that the Agency "should consider this study to be reliable for decision-making purposes."

Note: The lot number of the product identified in the QA Material Analysis Report in Attachment 3 of the laboratory study does not match the lot number of the product used during testing.

V RESULTS

MRID Number	Organism	Run	Carrier Type	No. Exhibiting Growth/ Total No. Tested
				Lot No. LA036838129- LB10014
469928-02	<i>Bacillus subtilis</i>	1	suture loops penicylinders	1° 0/60; 2° 0/60 1° 0/60; 2° 0/60
		2	suture loops penicylinders	1° 0/60; 2° 0/60 1° 0/60; 2° 0/60
		3	suture loops penicylinders	1° 0/60; 2° 0/60 1° 0/60; 2° 0/60
469928-02	<i>Clostridium sporogenes</i>	1	suture loops penicylinders	1° 0/60; 2° 0/60 1° 0/60; 2° 0/60
		2	suture loops penicylinders	1° 0/60; 2° 0/60 1° 0/60; 2° 0/60
		3	suture loops penicylinders	1° 0/60; 2° 0/60 1° 0/60; 2° 0/60
				Lot No. RT38310-0724
469928-03	<i>Bacillus subtilis</i>	1	suture loops penicylinders	0/60 0/60
		2	suture loops penicylinders	0/60 0/60
		3	suture loops penicylinders	0/60 0/60
469928-03	<i>Clostridium sporogenes</i>	1	suture loops penicylinders	0/60 0/60
		2	suture loops penicylinders	0/60 0/60
		3	suture loops penicylinders	0/60 0/60
469928-04	<i>Bacillus subtilis</i>	1	suture loops penicylinders	0/60 0/60
		2	suture loops penicylinders	0/60 0/60
		3	suture loops penicylinders	0/60 0/60
469928-04	<i>Clostridium sporogenes</i>	1	suture loops penicylinders	0/60 0/60
		2	suture loops penicylinders	0/60 0/60
		3	suture loops penicylinders	0/60 0/60

VI CONCLUSIONS

1. The submitted efficacy data (MRID No. 469928-02) do not support the use of the product, STERRAD Hydrogen Peroxide, when used in conjunction with the STERRAD 100S Sterilization System, as a sterilant against *Bacillus subtilis* and *Clostridium sporogenes*. Basic testing was conducted on 1 product lot in triplicate; 3 separate product lots were not tested. The product was tested in the specific device recommended for use. The product lot tested was at least 60 days old at the time of testing. Killing was observed in the subcultures of the required number of carriers (i.e., 60 carriers/2 types of surfaces) tested against the single product lot. Bacteriostasis controls were positive for growth. The positive controls (i.e., viability) were positive for growth. The negative controls (i.e., sterility) did not show growth. *Bacillus subtilis* and *Clostridium sporogenes* test spores (suture loops and penicylinders) showed resistance to acid for ≥ 2 minutes, in both primary and secondary subcultures. Confirmatory testing was not conducted. Biological indicator counts were not provided.

2. The submitted efficacy data (MRID Nos. 469928-03 and -04) do not support the use of the product, STERRAD Hydrogen Peroxide, when used in conjunction with the STERRAD NX Sterilization System, as a sterilant against *Bacillus subtilis* and *Clostridium sporogenes*. Basic testing was conducted on 1 product lot in triplicate; 3 separate product lots were not tested. The product was tested in the specific device recommended for use. The product lot tested was at least 60 days old at the time of testing. Killing was observed in the subcultures of the required number of carriers (i.e., 60 carriers/2 types of surfaces) tested against the single product lot. Bacteriostasis controls were positive for growth. Acid resistance testing was not conducted. Confirmatory testing was not conducted. Biological indicator counts were not provided. The applicant's own laboratory performed each of the tests, and stated that the studies were not performed in accordance with GLP standards.

VII RECOMMENDATIONS

A. Recommendations Regarding Proposed Label Claims

1. The applicant has not fully satisfied DIS/TSS-9 requirements for any one of the four sterilization systems. For three sterilization systems, efficacy testing was conducted on one (not three) product lots in triplicate. The applicant's representative claims that the sterilization systems are the same, except for the size of the units. [Note, however, that the sterilization systems have different cycle times (i.e., ranging from 28 minutes to 75 minutes) and do not necessarily require the injection of the same amount of the product. The applicant has not discussed how the systems are comparable, in light of these differences (and possibly other) operating parameters.] The applicant's representative has suggested that, considered collectively, data for three product lots has been provided.

2. No confirmatory data were provided.

3. The three efficacy studies previously reviewed (D285390) reported results for testing conducted on silk suture loops. The three recent efficacy studies (provided in this data package; D335346) report results for testing conducted on polyester suture loops. The laboratory study assigned MRID No. 469928-02 states that polyester suture loops are more suitable carriers (because high

concentrations of hydrogen peroxide may cause rapid oxidation of silk suture loops thus rendering them unusable).

4. Only one efficacy study provided was compliant with GLP standards (i.e., the laboratory study assigned MRID No. 469928-02). The applicant's representative suggests that the non-GLP efficacy studies are just as acceptable. The applicant's representative identifies deviations from GLP standards in the study assigned MRID No. 469928-05. All studies must be conducted under GLP.

5. Information in the user's guides suggests that the product (in conjunction with any of the four sterilization systems) may be used to sterilize medical devices for use in hospitals; however, the Agency's December 20, 2002 letter appears to prohibit this.

The following exhibit summarizes the efficacy studies provided to the Agency for the product, STERRAD Hydrogen Peroxide:

Sterilization System	Product Lot Number	No. of Carriers	Test Run in Triplicate?	Confirmatory Testing?	GLP?	Test Date
STERRAD 50 Sterilizer	5729	240 carriers (60 carriers, 2 types of surfaces, 2 microorganisms) Silk suture loops	Yes; 720 carriers total	No	No	199 6
STERRAD 100S Sterilizer	5729	240 carriers Silk suture loops	Yes; 720 carriers total	No	No	199 6
	LA0368 38129-LB1001 4	240 carriers Polyester suture loops	Yes; 720 carriers total	No	Yes	200 6
STERRAD 200 Sterilizer	9202	240 carriers Silk suture loops	Yes; 720 carriers total	No	No	199 9
STERRAD NX Sterilizer – Short Cycle	RT3831 0-0724	240 carriers Polyester suture loops	Yes; 720 carriers total	No	No	200 4
STERRAD NX Sterilizer – Advanced Cycle	RT3831 0-0724	240 carriers Polyester suture loops	Yes; 720 carriers total	No	No	200 4

B. Miscellaneous Label Recommendations

1. The "Storage and Disposal" section of the proposed label states that empty cassettes should be discarded per hospital policy. Please revise these instructions, for example, to state that empty cassettes should be discarded per policies of the institution or facility.

2. As previously requested in our letter (dated December 20, 2002), please add the following restriction statement to the proposed label: "Not for sale or use after (insert date here not more than 9 months after each manufacture date)."

3. Making the following changes would improve the proposed label:

- Under the "Physical and Chemical Hazards" section of the proposed label, change "Shoes clothing, or other" to read "Shoes, clothing, or other" and change "may be used to deactivate" to read "to deactivate."
- Under the "Environmental Hazards" section of the proposed label, change "ponds, estuaries oceans" to read "ponds, estuaries, oceans."
- Under the "Directions for Use" section, replace "in the in the original sleeve" to read "in the original sleeve" in the STERRAD 200 Sterilizer and STERRAD NX Sterilizer sections.
- Under the "Directions for Use" section, replace "Sterilizer Operator's Guide" with "Sterilization System User's Guide" and replace "Sterilizer Operator's Manual" with "Sterilization System User's Guide."

C. Recommendations Regarding the Sterilization System User's Guides

1. Our letter (dated December 20, 2002) states that the following statement should be inserted on the front page of all operator manuals:

"This product is not be used as a terminal sterilant/ high level disinfectant on any surface or instrument . . ."

The four user's guides that you have provided (i.e., STERRAD 50 Sterilization System User's Guide, STERRAD 100S Sterilization System User's Guide, STERRAD 200 Sterilization System User's Guide, and STERRAD NX Sterilization System User's Guide) have not been revised to include this statement. Please insert the above statement (in its entirety) on the front page of each of the four user's guides.

2. All four user's guides indicate that items appearing wet after a cancelled sterilization cycle should be wiped with a damp cloth. Please include appropriate instructions for disposing of the used cloths.

STERRAD 50 Sterilization System User's Guide

1. As per PR Notice 94-4, insert on the front page of all operator manuals, the following exact statement:

"This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membrane but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization of high level disinfection."

2. The personal safety and first aid instructions presented in the user's guide are similar, but not identical, to the first aid instructions on the proposed label. The label and user's guide language should be consistent.

3. The user's guide refers to fold-out pages and charts that unfold (e.g., page 8, page 24). The version of the user's guide provided did not include foldouts.

4. The user's guide does not describe how cassettes with unused hydrogen peroxide should be disposed. Please add appropriate instructions to the "Cassette Handling" section on page 18 of the user's guide.

5. Page 34 of the user's guide discusses manual cancellation of the sterilization cycle. Please revise the last statement on page 34 as follows because the items in the sterilization chamber may not have been sterilized: Change "and remove sterilized items" to read "and remove items in the sterilization chamber."

6. Page 39 of the user's guide discusses available options on the System Tools menu. Item 3 reads "Press the CASSETTE FUNCTIONS button." Please revise this phrase to read, for example, "Press the CASSETTE FUNCTIONS button to access tools for controlling certain actions of the cassette."

7. The charts for biological indicators contain acronyms that are not defined earlier in the user's guide (e.g., BI, TSB). Please define all acronyms used, even if believed to be well-known or common.

STERRAD 100S Sterilization System User's Guide

1. As per PR Notice 94-4, insert on the front page of all operator manuals, the following exact statement:

"This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membrane but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization of high level disinfection."

2. The personal safety and first aid instructions presented in the user's guide are similar, but not identical, to the first aid instructions on the proposed label. The label and user's guide language should be consistent.

3. The user's guide refers to a fold-out chart (e.g., page 6, page 20, page 21, page 28). The version of the user's guide provided did not include foldouts.

4. Page 17 of the user's guide discusses text identified by a check mark. Please replace the "4" in the last statement on page 17 with the "✓" symbol. Please review other pages of the user's guide as well (e.g., page 21, page 23) to ensure that text that should be identified by a "✓" is identified by a "✓" and not a "4."

5. The charts for biological indicators contain acronyms that are not defined earlier in the user's guide (e.g., BI, TSB). Please define all acronyms used, even if believed to be well-known or common.

6. Instructions for changing the cassette collection box (on pages 47-48) indicate that the cassette collection box should be disposed of according to local waste regulations, and that cassettes with unused hydrogen peroxide are subject to hazardous waste disposal regulations. Page 67 of the user's guide indicates that a cassette with an expired shelf-life exits to the collection box. If this were to happen, the collection box would contain a partially used cassette. ***The proper disposal of the collection box is now in question because the collection box could contain a cassette with unused hydrogen peroxide.*** Please explain and address this apparent inconsistency.

STERRAD 200 Sterilization System User's Guide

1. As per PR Notice 94-4, insert on the front page of all operator manuals, the following exact statement:

"This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membrane but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization of high level disinfection."

2. The personal safety and first aid instructions presented in the user's guide are similar, but not identical, to the first aid instructions on the proposed label. The label and user's guide language should be consistent.

3. The user's guide refers to a fold-out chart (e.g., page 22, page 24). The version of the user's guide provided did not include foldouts.

4. The user's guide does not describe how cassettes with unused hydrogen peroxide should be disposed. Please add appropriate instructions to the "Cassette Handling" section on page 18 of the user's guide.

STERRAD NX Sterilization System User's Guide

1. As per PR Notice 94-4, insert on the front page of all operator manuals, the following exact statement:

"This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membrane but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization of high level disinfection."

2. The personal safety and first aid instructions presented in the user's guide are similar, but not identical, to the first aid instructions on the proposed label. The label and user's guide language should be consistent.

3. The user's guide refers to a fold-out chart (e.g., page 11, page 27). The version of the user's guide provided did not include foldouts.

4. In most instances, the user's guide states that gloves should be worn when handling items from any load containing moisture. Please revise these instructions to specify the use of latex or vinyl gloves and that the operator should wipe off items with a damp cloth.

5. Page 52 of the user's guide indicates that a cassette (used or unused) can be manually "moved" to the cassette drawer. If this were to happen to an unused or partially used cassette, the cassette disposal box would contain a cassette containing unused hydrogen peroxide. ***The proper disposal of the cassette disposal box is now in question because the cassette disposal box would contain a cassette with unused hydrogen peroxide.*** Please explain and address this apparent inconsistency.

6. The user's guide contains a number of sentences with obviously missing words (e.g., Refer the "Maintenance" chapter for additional information." Please re-read the user's guide carefully to find and correct these errors.

DATA PACKAGE BEAN SHEET

Date: 02-Oct-2007

Page 1 of 2

Decision #: 372392

DP #: (344717)

PRIA

Parent DP#:

*** Registration Information ***

Registration: 71871-G - STERRAD HYDROGEN PEROXIDE

Company: 71871 - ADVANCED STERILIZATION PRODUCTS

Risk Manager: RM 33 - Marshall Swindell - (703) 308-6341 Room# PY1 S-8828

Risk Manager Reviewer: Martha Terry MTERRY

Sent Date:

Calculated Due Date: 11-Oct-2007

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A54) NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM) USES;

Ingredients: 000595, Hydrogen peroxide(59%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 02-Oct-2007

Due Back:

DP Ingredient: 000595, Hydrogen peroxide

DP Title: Product Chemistry Data

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: AD / PSB

Team Name: CTT

Reviewer Name:

Contractor Name:

10/9/07

10/9/07

10/10/07

1/29/08

1/28/08

Last Possible Science Due Date: 02-Jan-2008

Science Due Date: 01-Jan-2008

Sub Data Package Due Date: 1/7/08

*** Studies Sent for Review ***

No Studies

*** Additional Data Package for this Decision ***

Printed on Page 2

*** Data Package Instructions ***

Please review the product chemistry data in support of the Pria application. As per letter and email from company (see attached copies), the data (MRID #S 456808-01 THRU 456808-05, and MRID # 469928-01) was previously submitted to the Agency and was not reviewed. A copy of the data is attached along with a copy of the label, CSF, previous science review and other information. Thanks

Please note that the company has a new due date of 2/1/08 to complete all of the data requirements for this product registration.

PRIA A 54

Subm #817516

Sci due 1/1/08

Admin. due 2/1/08

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460



OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES
Antimicrobial Division

02/22/07

TO: Marshall Swindell / Martha Terry
PM Team 33
FROM: Juan F. Negrón, Chemist *JFN*
Product Science Branch, CT Team
Antimicrobial Division (7510P)
THRU: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobial Division (7510C)
THRU: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobial Division (7510C)

A handwritten signature in blue ink, likely belonging to Karen P. Hicks, written over the "THRU:" line.

APPLICANT: Advanced Sterilization Products
Action code: A54
Due date: 04/11/07

Product Formulation
Active Ingredient(s)

	% by wt.
Hydrogen peroxide	59.0

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460



OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES
Antimicrobial Division

02/22/07

DP BARCODE: D335345

MRID: 469928-01

SUBJECT: STERRAD® Hydrogen Peroxide

REG. NO. OR FILE SYMBOL: 71871-G

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use ☐ OR End-use Product ☒

INGREDIENTS (PC Codes) Hydrogen peroxide (000595)

CAS Number: (7722-84-1)

TEST LAB: Truesdail Laboratories, Inc.

SUBMITTER: Advanced Sterilization Products

GUIDELINE: 830 Guidelines

COMMODITIES: Formulation

REVIEWER: Juan F. Negrón ORGANIZATION: AD

APPROVER: Karen P. Hicks APPROVED DATE: 2/22/07

COMMENT:

BACKGROUND:

On behalf of the registrant, Advanced Sterilization Products, Lewis & Harrison Consultants is submitting a new product for registration. The non-integrated end-use product, STERRAD® Hydrogen Peroxide, is to be used in the sterilization of laboratory and industrial equipment.

FINDINGS:

1. The Product Chemistry Reviewer has received the following documents:
 - A letter, dated 11/02/06.
 - A label, dated 11/21/06 pin punch.
 - Confidential Statement of Formula (CSF), dated 11/02/06, for the basic formulation.
 - A study title, "Physical and Chemical Characteristics for Sterrad Hydrogen Peroxide; Flammability & Corrosion Characteristics." Volume 1, MRID # 469928-01.
 - A study title, "STERRAD® 50 Sterilization System." User's Guide.
 - A study title, "STERRAD® 100 Sterilization System." User's Guide.
 - A study title, "STERRAD® 200 Sterilization System." User's Guide.
 - A study title, "STERRAD® NX™ Sterilization System." User's Guide.
2. The CSF, dated 11/02/06, for the basic formulation is revised.
3. The CSF and the label have the same nominal.
4. The registrant submitted 830.6315 & 830.6320 guidelines. The 830.6320 Corrosion Characteristic is a partial study since this guideline should be conducted along with the 830.6317 guideline for a one year study.
5. Registrant did not submit a complete package of the 830 guidelines Group "A & B." See table below.
6. The registrant submitted user's guide that provides information on how to use the system.

RECOMMENDATIONS:

1. The registrant needs to submit the 830 guidelines Group "A & B." Registrant needs to be aware that some of these guidelines are not applicable to the product. See table below for data gap of the 830 guidelines.

CONCLUSION:

The CSF, dated 11/02/06, for the basic formulation is acceptable. The registrant needs to submit a complete package for the 830 guideline.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system [X]
- Are all TGAs used registered? Yes [] No []
- Integrated formulation system []
- If "ME-TOO," specify EPA Reg. No. of existing product: _____

b. Clearance of inerts for non-food or food use:

The product is cleared for food use under 40 CFR §§180.940 and 180.950.
Yes [x] No []

c. Physical state of product: Liquid

- #### d. The chemical IDs and analytical information (including that for the TGAs), density, pH, and flammability are consistent with that given in 830 Series, Group B.
- Yes [] No [] (Insufficient data to make a statement.)

- #### e. The NCs and CLs are acceptable.
- Yes [X] No []

f. Active ingredient(s)	<u>NC</u>	<u>LCL</u>	<u>UCL</u>
	(%)	(%)	(%)
Hydrogen Peroxide	59.0	56.5	60.77

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
Yes [] No [] Not applicable [X]
- Have all impurities of $\geq 0.1\%$ in the product been identified?
Yes [] No [] Not applicable [X]

II PRODUCT LABEL

a. The active ingredient(s) statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes ☐ No ☐

b. The formula contains one of the following:

- | | | |
|--|------------------------------|--|
| • 10% or more of a petroleum distillate: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • 1.0% or more of methyl alcohol: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • sodium nitrite at any level: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • a toxic List 1 inert at any level: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • arsenic in any form: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes ☐ No ☐ Not applicable ☒

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.

Yes ☐ No ☐ Not applicable ☒

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.

Yes ☐ No ☐

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).

Yes ☐ No ☐

Note: Storage stability studies are ongoing and have not been completed.

Table A:
Product Chemistry (830 Series, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity ¹	G	
830.1600 Description of Materials	G	
830.1620 Production Process ²	NA	
830.1650 Formulation Process ³	G	
830.1670 Formation of Impurities ⁴	NA	
830.1700 Preliminary Analysis ⁵	NA	
830.1750 Certified Limits ⁶	G	
830.1800 Analytical Method ⁷	G	
830.1900 Submittal of Samples	[Samples are to be provided upon request.]	

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

¹See Confidential Appendix A for additional information

²For MP/EP products produced by an integrated formulation system.

³For products from a TGAI or MP.

⁴May be waived unless actual/possible impurities are of toxicological concern.

⁵Five batch analysis required for products produced by an integrated formulation system.

⁶If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

⁷Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color			
830.6303 Physical State	G		
830.6304 Odor	NA		
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NA		
830.6314 Oxidation/Reduction; Chemical Incompatibility	G		
830.6315 Flammability/Flame Extension	A	< 210 °F Flashpoint.	469928-01
830.6316 Explodability	G		
830.6317 Storage Stability	G		
830.6319 Miscibility ¹	G		
830.6320 Corrosion Characteristics	U	Accelerated study shows no reaction to the package.	469928-01
830.6321 Dielectric Breakdown Voltage	G		
830.7000 pH ²	G		
830.7050 UV/Visible Absorption	NA		
830.7100 Viscosity	G		
830.7200 Melting Point/Melting Range	NA		
830.7220 Boiling Point/Boiling Range	NA		
830.7300 Density/Relative Density/Bulk Density	G		
830.7370 Dissociation Constants in Water	NA		
830.7550/830.7560/830.7570 Partition Coefficient	NA		
830.7840/830.7860 Water Solubility	NA		
830.7950 Vapor Pressure	NA		

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

¹If product is an emulsifiable liquid

²If product is dispersible with water



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

November 28, 2006

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT
Or Pay On-Line at www.Pay.Gov (See Below for Details)

OPP Decision Number: D-372392
EPA File Symbol or Registration Number: 71871-G
Product Name: STERRAD HYDROGEN PEROXIDE
EPA Receipt Date: 21-Nov-2006
EPA Company Number: 71871
Company Name: ADVANCED STERILIZATION PRODUCTS

Ana Rodriquez-Koster
LEWIS & HARRISON
ADVANCED STERILIZATION PRODUCTS
122 C ST NW STE 740
WASHINGTON, DC 20001

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application for registration. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A54

NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM) USES;

Please remit payment in the amount of: \$ 4,200 to:

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USEPA Washington Finance Center
Pesticide Registration Service Fee
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By Courier:

U.S. EPA Washington Finance Center
Pesticide Registration Service Fee
C/O Mellon Client Service Center
500 Ross Street, Room 670
Box 360277
Pittsburgh, PA 15251-6277
Attn: EPA Module Supervisor
Telephone: (412) 236-2294

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

Effective November 1, 2006, fees may be paid on-line via credit card or electronic fund transfer. To submit a payment on-line, visit www.pay.gov. From the pay.gov home page, select "search by form name." From the next page, select "P," then click on "Pesticide Registration Improvement Act. Fee Payment" and complete the form, making certain to use the decision number and registration number on the invoice you receive from the Pesticide Program in the space provided.

You may be eligible for a full or partial waiver of the registration service fee if, for example, you qualify as a small business or are applying for a minor use, or if your application is solely associated with an IR-4 tolerance petition. Please be advised that if you intend to request a waiver, you must do so in writing within 15 days of receipt of this invoice instead of remitting the amount indicated above. OPP will not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how to request and document a fee waiver is available on the OPP Fee for Service web site at www.epa.gov/pesticides/fees.

Please send Registration Service Fee Waiver requests to:

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Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
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Washington, DC 20460

By Courier:

Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall #2
1801 S. Bell St.
Arlington, VA 22202

A PRIA decision time review period will not start until a fee waiver is granted and/or the Agency receives certification that the outstanding fee has been paid. If the Agency does not receive certification of payment for this action or a fee waiver request within the next 45 days, the Agency will presume that you no longer want to pursue this action. The Agency will then initiate a process that may result in administrative withdrawal of this action.

If you have any questions, please contact the Pesticide Registration Service Fee

Ombudsman at (703) 308-6432.

Sincerely,

Teresa Downs

Front End Processing Staff

Information Technology & Resources Management Division

ATTACHMENT 4

Summary of Efficacy Studies Conducted with STERRAD Hydrogen Peroxide

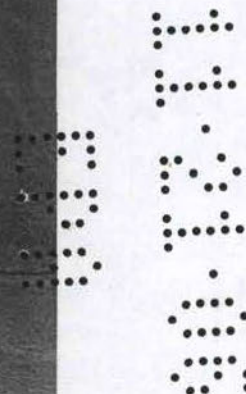


Table 1 below summarizes all the previously submitted and new efficacy studies that have been conducted with STERRAD Hydrogen Peroxide in association with the various STERRAD Sterilization System units.

TABLE 1
Summary of Agency Previously Submitted and New Efficacy Studies Conducted with
STERRAD Hydrogen Peroxide

Study (Identified by MRID# if available)	Sterilization System Used	Tested Organism	Number of Product Lots Tested	Age of Tested Product Lot(s)	Results
<u>AOAC Test for Sterrad 50 Sterilization System</u> (1996) Study ID# RPT-01422 MRID# 45680806	Sterrad 50 Sterilization System	B. subtilis C. sporogenes	Lot# 5729	> 60 days old	Passed
<u>AOAC Test for Sterrad 100S Sterilization System</u> (1996) Study ID# RPT-01426 MRID# 45680807	Sterrad 100S Sterilization System	B. subtilis C. sporogenes	Lot# 5729	> 60 days old	Passed
<u>AOAC Test for Sterrad 200 Sterilization System</u> (1996) Study ID# RPT-01821 MRID# 45680808	Sterrad 200 Sterilization System	B. subtilis C. sporogenes	Lot# 9202	Not known	Passed
<u>AOAC Sporidical Activity of Disinfectants Test in Sterrad 100S Sterilization System for EPA Registration Using Sterrad Hydrogen Peroxide</u> (2006) Study ID# EPA 100's MRID# 46992802	Sterrad 100S Sterilization System	B. subtilis C. sporogenes	Lot# LA036838129-LB10014	< 60 days old	Passed
<u>AOAC Sporidical Activity of Disinfectants Test in the STERRAD 100S Sterilization System for EPA Registration Using STERRAD Hydrogen Peroxide</u> 472677-01 MRID# Not Yet Assigned	Sterrad 100S Sterilization System	B. Subtilis C. sporogenes	Lot #'s LA057847229 - LB10082 and LA017844600-LB10040	Both lots > 60 days old	Passed
<u>AOAC Test for Sterrad NX Sterilization System in Short Cycle</u> (2004) Study ID# RPT-02400 MRID# Not Yet Assigned	Sterrad NX Sterilization System	B. subtilis C. sporogenes	Lot# RT38310-0724 Lot# RT 39861-0914	Lot# RT38310-0724 > 60 days old	Passed
<u>AOAC Test for Sterrad NX Sterilization System in Long Cycle</u> (2004) Study ID# RPT-02397 MRID# Not Yet Assigned	Sterrad NX Sterilization System	B. subtilis C. sporogenes	Lot# RT38310-0724 Lot# RT 39861-0914 Lot# RT 39861-1204	Lot# RT38310-0724 > 60 days old	Passed

STERRAD[®] 50 Sterilization System User's Guide



ACCEPTED
with COMMENTS
EPA Letter Dated:

FEB 1 2008

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

71871-3
114

STERRAD[®] 50 Sterilization System

User's Guide

REF 99015

Manufacturer:

ASP ADVANCED STERILIZATION PRODUCTS[®]
a *Johnson & Johnson* company

Division of Ethicon, Inc.

33 Technology Drive, Irvine, CA 92618-9824

Authorized EC Representative
Ethicon GmbH

Oststraße 1, D-22844 Norderstedt



0123

USA	Irvine, CA 92618	I	00040 Pomezia, Roma
F	92787 Issy-les-Moulineaux	E	28042 Campo de las Naciones, Madrid
D	22844 Norderstedt	GB	Ascot, Berks
CH	8957 Spreitenbach	CDN	Johnson & Johnson Medical Products Markham, ON, L3R 0T5
NL	3800 AD Amersfoort	J	東京港区東田町 6-3-2 輸入・販売元 ジョーンズ・エンド・ジョンソン 株式会社
BR	Rodovia Dutra, Km 154 S.J. Campos S.P. 12237-350	A	1190 Wien
S	19184 Sollentuna	GR	15125 Maroussi, Athens

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EPA Letter Dated:

08-04545-2-002

LC 10050-602 Rev D

FEB 1 2008

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

STERRAD[®] 50 User's Guide

71871-3

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About This Guide

- *In this chapter . . .*
 - *information about this user's guide*

Overview

This guide is designed to provide useful information on the day-to-day operation and routine maintenance of the STERRAD® 50 Sterilizer.

The guide is divided into 6 chapters and 2 appendices and two fold-out pages. These chapters provide information on using the sterilizer, load preparation, routine maintenance, and troubleshooting the system should problems arise.

The chapters are:

- **About This Guide**-this section gives you important information on how to get the most use out of this guide.
- **Chapter 1. Introduction**-the first chapter of the guide has important details about the STERRAD 50 Sterilizer, including the major parts of the sterilizer and STERRAD Process information.
- **Chapter 2. For Your Safety**-this may be the most important chapter in the guide. You should read this chapter thoroughly, understand the information, and follow all the safety procedures. These safety procedures include safe handling of cassettes, safe handling of the load and first aid information in case of possible hydrogen peroxide exposure.
- **Chapter 3. Preparing Items To Be Sterilized**-this chapter provides a brief description on preparing items to be sterilized, and how to effectively package the load.
- **Chapter 4. Day-to-Day Operation**-this chapter gives you detailed information on how to use the sterilizer, how to load the chamber, how to use the control panel, how to run cycles and how to interpret BI test results.
- **Chapter 5. Routine Maintenance**-the routine maintenance of the STERRAD 50 Sterilizer is very minimal. This chapter shows you how to change the printer paper and ribbon, and what steps to follow to keep the sterilizer clean.

- **Chapter 6. Troubleshooting**-the STERRAD 50 Sterilizer displays a number of messages indicating system status at any given moment. Many of these messages do not require any action from you. Others require that you call your ASP Service Representative for maintenance. The messages are listed in alphabetical order.
- **Appendix A. Specifications**-this appendix details the technical specification information for your sterilizer.
- **Appendix B. Service and Commercial Warrantees**-this appendix contains the detailed system warranty and our guarantees to you regarding your STERRAD 50 Sterilizer.

Chapter 1. Introduction

In this chapter . . .

- *operation information*

Overview

The STERRAD® 50 Sterilization System is a general purpose, low temperature sterilizer using the STERRAD Process to inactivate microorganisms on a broad range of medical devices and surgical instruments. This sterilizer offers an effective, safe, fast, economical, easy to use, reliable and flexible sterilization method.

It is your responsibility to read, understand, and follow the safety information presented in chapter 2 and throughout this guide. The safety information is provided for your benefit and for the benefit of your instruments and equipment.

Operation Information

This guide provides basic information on how to operate the STERRAD 50 Sterilizer safely and efficiently. As a medical professional, you may already be familiar with general sterilization principles. However, the STERRAD 50 Sterilizer represents a new technology, and it requires special attention to the ways in which it differs from other sterilizers.

The STERRAD 50 Sterilizer has been developed by Advanced Sterilization Products, a Johnson and Johnson Company, a division of Ethicon, Inc., to sterilize medical devices by diffusing hydrogen peroxide into the chamber and then “exciting” the hydrogen peroxide molecules into a plasma state. The combined use of hydrogen peroxide vapor and plasma safely and rapidly sterilizes medical instruments and materials without leaving toxic residues. All stages of the sterilization cycle, including the plasma stage, operate within a dry environment at a low temperature, and thus the cycle is not damaging to compatible instruments sensitive to heat and moisture. The STERRAD 50 Sterilizer can be used for both metal and nonmetal devices, and can also sterilize instruments that have difficult-to-reach (diffusion-restricted) spaces, such as hinges on forceps.

The system consistently provides a sterility assurance level (SAL) of 10^{-6} , as defined by FDA and international standards, for clinical use on all allowed substrates within the limits of the claims for materials and geometries when used in accordance with the directions in this guide.

The length of all cycle phases and the setpoints for all critical process parameters are controlled by a microprocessor and software. The system reliably sterilizes various materials and load configurations, without leaving toxic residue when used in accordance with the directions in this guide.

✓ *Note: The following paragraph presents a simplified overview of the sterilizer components. Chapters 3 and 4 detail loading and sterilizer operation.*

The main sterilizer components are shown in the following illustration: The sterilizer operates as follows:

- the system indicates that sterilization can start by displaying the "Ready to Use" message on the system display.
- the items to be sterilized are placed in the chamber.
- the door is manually shut.
- a cassette is inserted (if needed).
- START is pressed.

The sterilization process is complete in about 45 minutes. The load can then be used immediately or stored according to your procedures.

1 Introduction

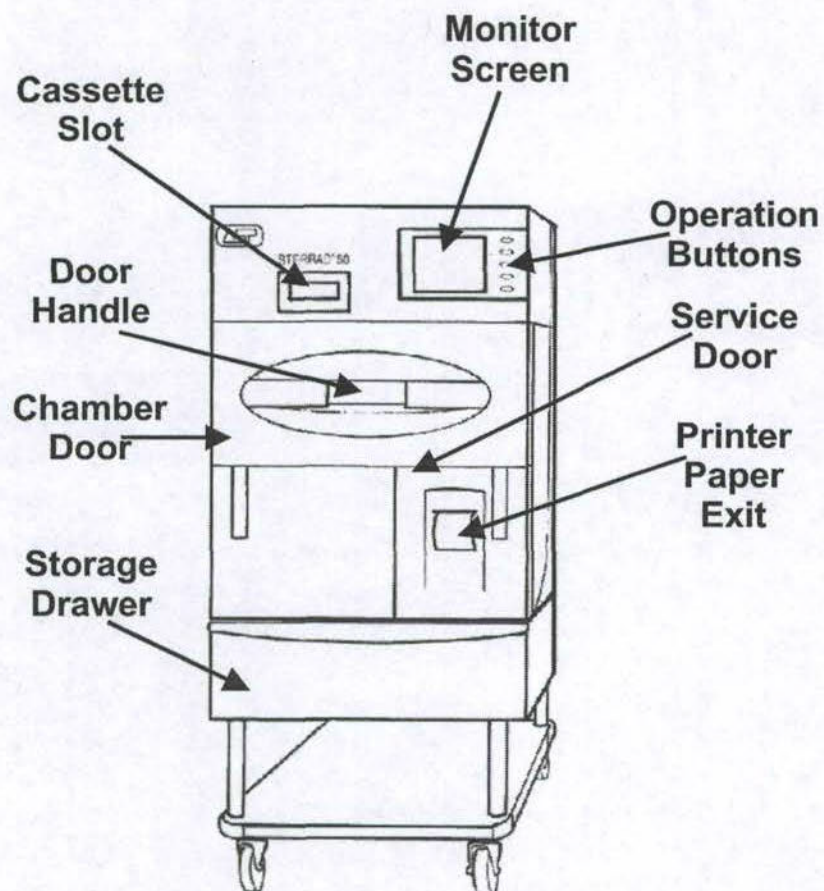


Figure 1. STERRAD® 50 Sterilizer

Chapter 2. For Your Safety

In this chapter . . .

- *personal safety and first aid*
- *device safety*
- *cassette handling*
- *safe handling*

Overview

Your safety is of primary concern to ASP. This section provides information on safely using the sterilizer. **You must read, understand and use the information in this chapter before operating the unit.** Also, always pay attention to the warnings, cautions and notes throughout this guide. This information is for your safety and to ensure that you receive the most benefit from the safe operation of your STERRAD® 50 Sterilization System. Only trained, experienced technicians, who are fully acquainted with the unit, should repair or adjust the STERRAD 50 System.

Personal Safety and First Aid

- **WEAR LATEX, PVC (VINYL) OR NITRILE GLOVES WHILE REMOVING ITEMS FROM THE STERILIZER AFTER A CYCLE HAS CANCELLED. CONCENTRATED HYDROGEN PEROXIDE IS CORROSIVE TO SKIN, EYES, NOSE, THROAT, LUNGS, AND GASTROINTESTINAL TRACT.** If a cycle cancels and the items in the load have any visible moisture or liquid, hydrogen peroxide may be present.
- Direct hydrogen peroxide contact with the skin can cause severe irritation. If skin contact occurs, immediately flush with large amounts of water. If symptoms are severe or persist, consult a physician immediately.
- Direct hydrogen peroxide contact with eyes can cause irreversible tissue damage. If eye contact occurs, immediately flush with large amounts of water and immediately consult a physician.
- Inhalation of vapor or mist can cause severe irritation of lungs, throat, and nose. If inhalation occurs, move to fresh air and consult a physician immediately.
- Ingestion can produce corrosion that may be life threatening. If swallowed, drink plenty of water immediately to dilute. Do not induce vomiting. Consult a physician.

Device Safety

- **DO NOT ATTEMPT TO STERILIZE ITEMS OR MATERIALS THAT DO NOT COMPLY WITH THE DIRECTIONS SPECIFIED IN THIS GUIDE.** In addition, you should read the medical device manufacturer's instructions, or call your ASP representative to determine whether an item can be sterilized by this unit.
- All items must be cleaned and thoroughly dried before loading into the sterilizer. Loads containing moisture may cause cycle cancellation.
- The chapter on preparing items to be sterilized contains information about which materials and devices can be processed by the STERRAD Sterilizer.
- Metal objects must not come into contact with the chamber walls, the door, or the electrode. Contact with the walls, door, or electrode could damage the sterilizer or instruments.
- Prior to relocating the STERRAD Sterilizer, make sure the new power source has a dedicated line with the correct power requirements for your location (see Appendix A for electrical information.)
- Do not leave the sterilizer unplugged or turned off for longer than 24 hours. If the sterilizer must be turned off for longer than 24 hours, call your ASP Service Representative for instructions.
- Only ASP-approved biological indicators should be used to monitor the sterilization cycle. Should a cancellation occur when one of these biological indicators is in the chamber, it should be discarded and a new biological indicator should be used when re-starting the cycle. Call your ASP representative for information on approved biological indicators.

Cassette Handling

- **STERRAD 50 CASSETTES CONTAIN CONCENTRATED HYDROGEN PEROXIDE, A STRONG OXIDIZER. CONCENTRATED HYDROGEN PEROXIDE IS CORROSIVE TO SKIN, EYES, NOSE, THROAT, LUNGS, AND GASTROINTESTINAL TRACT.** Direct contact with the skin can cause severe irritation. If skin contact occurs, immediately flush with large amounts of water. If symptoms are severe or persist, consult a physician immediately. Direct contact with eyes can cause irreversible tissue damage. If eye contact occurs, immediately flush with large amounts of water and immediately consult a physician. Inhalation of vapor or mist can cause severe irritation of lungs, throat, and nose. If inhalation occurs, move to fresh air and consult a physician immediately. Ingestion can produce corrosion that may be life threatening. If swallowed, drink plenty of water immediately to dilute. Do not induce vomiting. Consult a physician.
- Do not remove the plastic wrapper from the cassette package if the indicator strip is red. Red indicates that the cassette might have been damaged. Call your ASP Representative for credit.
- Do not remove used cassettes from the protective cardboard sleeve. Dispose of the cassette inside the protective sleeve in normal waste or follow your facility's procedures. Empty or expired cassettes must be replaced prior to starting the cycle.
- If the USED cassette falls out of the cardboard sleeve, wear latex, PVC (vinyl), or nitrile gloves to place the plastic cassette back in the original sleeve. Discard the cassette according to your hospital procedures. Do not touch gloves to face or eyes.

Safe Maintenance

- Repairs and adjustments should only be attempted by experienced technicians who are fully trained to maintain and repair the STERRAD 50 Sterilizer.
- Use of unauthorized parts for maintenance or repair could cause personal injury, result in costly damage or unit malfunction, and void the warranty.
- The power cord of the STERRAD 50 Sterilizer should only be plugged into outlet that have been approved by a qualified technician. For further

requirements, refer to the label on the back panel of the sterilizer or call your ASP service representative.

- Do not clean the chamber door area with abrasives. The sterilization chamber uses an O-ring vacuum seal to maintain a vacuum in the chamber. Never use rough cleaning tools, such as a wire brush or steel wool, on the door housing or chamber assembly. This could damage the seal.

Additional Information

The information in this chapter is repeated where appropriate throughout this guide for your safety and use. This information is subsequently labeled: **WARNINGS**, **Cautions** or **Notes** as appropriate.

- **WARNINGS** are shown in the text in all bold upper case letters. They indicate events or conditions that can result in serious injury or death.
- **Cautions** are shown in the text in bold letters, and they indicate events or conditions that can result in damage to equipment.
- Notes are shown in the text with a check mark ✓. Notes highlight specific information about the proper use and maintenance of the STERRAD 50 Sterilizer.

Chapter 3.

Preparing Items To Be Sterilized

In this chapter . . .

- *indications for use*
- *recommended materials*
- *typical items sterilized*
- *items not recommended*
- *cleaning, rinsing, and drying*
- *guidelines for wrapping, packaging, and loading*

3

Preparing Items To Be Sterilized

Overview

This chapter briefly describes the materials and devices that can be sterilized by the STERRAD® 50 Sterilizer. It also provides information on how to prepare items for sterilization.

STERRAD 50 Sterilizers can process many of the items you commonly sterilize as well as instruments that are sensitive to heat and moisture. However, there are a few important exceptions. Please review the "How to Determine What Can Be Sterilized in the STERRAD 50 System" fold-out page contained in this chapter. It contains details on recommended materials and lumen sizes.

Indications for Use

The STERRAD 50 Sterilizer is designed for sterilization of both metal and nonmetal medical devices at low temperatures. Because the cycle operates within a dry environment and at low temperatures, it is especially suitable for instruments sensitive to heat and moisture. (See the list of recommended materials.)

The STERRAD 50 Sterilizer can sterilize instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors.

Devices with Metal Lumens

Medical devices that have a single stainless steel lumen that has:

- an inside diameter of ≥ 1 mm and a length of ≤ 125 mm,
- an inside diameter of ≥ 2 mm and a length of ≤ 250 mm,
- an inside diameter of ≥ 3 mm and a length of ≤ 400 mm,

can be processed in the STERRAD 50 Sterilizer without a STERRAD Booster/Adaptor.

Medical devices that have a single stainless steel lumen that has:

- an inside diameter of ≥ 1 mm and a length > 125 mm and ≤ 500 mm,
- an inside diameter of ≥ 2 mm and a length > 250 mm and ≤ 500 mm,
- an inside diameter of ≥ 3 mm and a length of > 400 mm and ≤ 500 mm,

must be processed in the STERRAD 50 Sterilizer with a STERRAD Booster/Adaptor.

Medical devices with a lumen made of copper containing alloys, such as Monel, having an inside diameter of ≥ 3 mm, and a length of ≤ 500 mm, **must** be processed with a STERRAD Booster/Adaptor in the STERRAD 50 Sterilizer.

Devices with Nonmetal Lumens

Reprocessable medical devices that have a polyethylene or Teflon® (PTFE) lumen (medical tubing) having the following dimensions can be processed in the STERRAD 50 Sterilizer:

- an inside diameter of ≥ 1 mm and a length of ≤ 1000 mm can be processed without a STERRAD Booster/Adaptor,
- an inside diameter of ≥ 1 mm and a length of ≤ 2000 mm **must** be processed with a STERRAD Booster/Adaptor.

Flexible endoscopes with lumens made from polyethylene or Teflon® and an inside diameter of ≥ 1 mm and a length of ≤ 2000 mm **must** be processed in the STERRAD 50 Sterilizer with a STERRAD Booster/Adaptor attached to each lumen.

WARNING! DO NOT ATTEMPT TO STERILIZE ITEMS OR MATERIALS THAT DO NOT COMPLY WITH THE DIRECTIONS SPECIFIED IN THIS GUIDE. IN ADDITION YOU SHOULD READ THE MEDICAL DEVICE MANUFACTURER'S INSTRUCTIONS OR CALL YOUR ASP REPRESENTATIVE TO DETERMINE WHETHER AN ITEM CAN BE STERILIZED BY THIS STERILIZER.

Teflon® is a registered trademark of the DuPont Corporation.

How to Determine What Can be Sterilized in the STERRAD[®] 50 System

The following page is a chart that unfolds to show you detailed lists of recommended items, materials, and some typical devices that can be sterilized in the STERRAD 50 Sterilizer. Be sure to check with the medical device manufacturer's instruction before loading any new item in the STERRAD 50 Sterilizer.

✓ *Note: There are a wide variety of material and devices that can be sterilized in the STERRAD 50 Sterilizer. As more manufacturers complete testing of their products with STERRAD Sterilizers, the range of recommended and/or compatible items grows. Because of that, the information in the table included in this publication will be updated as new information becomes available. ASP maintains this updated information and we are happy to share it with you. Please contact your ASP Representative for an up-to-date list of recommended materials, devices and/or device manufacturer information or visit the ASP website at www.sterrad.com.*

Items Not Recommended

- Instrument mats other than STERRAD Instrument Mats.
- Instrument trays other than STERRAD Instrument Trays or APTIMAX™ Instrument Trays.
- Any item that is not completely dry.
- Items or materials that absorb liquids.
- Items made of materials that contain cellulose, such as cotton, paper or cardboard, linens, huck towels, gauze sponges, or any item containing wood pulp.
- Paper instrument count sheets or lot stickers.
- Liquids and powders.
- Items with mated, Nylon® surfaces.
- Single use items for which the manufacturer does not recommend resterilization.
- Implants for which the manufacturer has not specifically recommended sterilization in the STERRAD 50 Sterilizer.
- Instruments and devices that can not withstand a vacuum and are labeled for gravity steam sterilization methods.
- Items whose design permits the surfaces to collapse onto each other unless some method is used to keep the surfaces separated.
- Devices with internal parts, such as sealed bearings, that cannot be immersed may present difficulties in cleaning and should not be processed in the STERRAD 50 Sterilizer.

Nylon® is a registered trademark of the DuPont Corporation.

Cleaning, Rinsing, and Drying

✓ *Note: All items must first be cleaned, rinsed, and thoroughly dried before being placed in the sterilizer*

Cleaning and sterilization are two separate processes. Thorough cleaning is essential for assurance of sterilization by all sterilization methods, including the STERRAD Sterilization System.

The process of cleaning is necessary to remove organic and inorganic soil and debris from equipment. In this process, many of the microorganisms are removed from the surface of the instrument. The process of sterilization inactivates all of the remaining spores and living microorganisms.

- Remove all blood, tissue, and soil from items by following the device manufacturer's instructions using an appropriate detergent or cleanser.
- Rinse items thoroughly to remove detergent or cleanser residue.
- Dry all items thoroughly. It is necessary to remove moisture from all parts of the items. Only dry items should be loaded into the sterilization chamber.

✓ *Note: Loads containing moisture may cause a cycle cancellation.*

CAUTION: *As with any disinfectant/cleaning/sterilization system, periodic careful inspection of the devices after repeated exposure to the disinfectant/cleaner/sterilant is necessary, due to potential damaging effects of the chemical agent on the devices.*

Guidelines for Wrapping, Packaging, and Loading

Proper preparation of trays, pouches, and instruments can minimize or prevent cycle cancellation due to load-related problems.

- Only STERRAD Instrument Trays, APTIMAX™ Instrument Trays and STERRAD Accessories are recommended for use in the STERRAD 50 Sterilizer. STERRAD Instrument Trays and APTIMAX™ Instrument Trays are specially designed to allow diffusion of hydrogen peroxide and the plasma around all the items in the load. The trays should only be padded with STERRAD Instrument Tray Mats or polypropylene sterilization wrap. Do NOT use linen, cellulosic, or any materials shown in the "Items Not Recommended" list.
- Do not stack trays. Do not stack trays within trays.

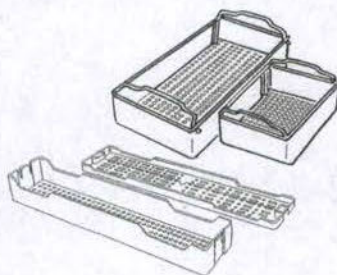


Figure 2. Use only STERRAD® Instrument Trays and APTIMAX™ Instrument Trays

- Improper loading of the sterilizer may result in cycle cancellations and/or positive biological indicator results.
- Do not use foam pads in instrument trays. They may absorb the hydrogen peroxide.
- Do not use any wraps or packaging that are not approved by ASP and listed in the previous section on "items not recommended."

3

Preparing Items To Be Sterilized

- Use only STERRAD 50 Sterilizer compatible polypropylene sterilization wrap and Tyvek® pouches. Do not use paper pouches or sterilization wraps containing cellulose or cotton.
- Place STERRAD Chemical Indicator Strips inside trays and Tyvek® pouches.
- Secure all wraps with STERRAD Chemical Indicator Tape.
- Arrange items to ensure that the hydrogen peroxide and plasma can contact all surfaces.
- Place peel pouches loosely on edge, if possible. Arrange them so that the transparent side of a pouch faces the opaque side of the next pouch.
- Do not allow any item to touch the walls of the sterilization chamber, door, or electrode.

CAUTION: *Metal objects should not come into contact with the walls of the sterilization chamber, door, or electrode. Contact with the walls, door, or electrode can interrupt the plasma phase of the process, cause a cycle cancellation, and/or damage the item or the sterilizer.*

- Provide at least 25 mm (1 inch) of space between the electrode and the load.
- Place a STERRAD CycleSure™ Biological Indicator or STERRAD Biological Indicator Test Pack in the chamber. Frequency of biological testing should be at least once per day or in accordance with your hospital policy. Review the instructions included with the biological indicator to ensure proper use.
- Proceed to "Chapter 4. Day-to-Day Operation" for information on starting a cycle.

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Chapter 4.

Day-to-Day Operation

In this chapter . . .

- *safe operation*
- *sterilizer operation*
- *system displays*
- *preparing the load*
- *loading the sterilization chamber*
- *inserting a cassette*
- *sterilization cycles*
- *unloading and handling*
- *rebooting/ power switch*

Safe Operation

Before operating your STERRAD® Sterilizer, be sure you thoroughly *read, understand, and follow* the information in “Chapter 2. For Your Safety” as well as “Chapter 3. Preparing Items To Be Sterilized” and the “How to Determine What Can be Sterilized in the STERRAD System” fold-out in Chapter 3.

Sterilizer Operation

The STERRAD 50 Sterilizer automatically monitors and controls the sterilization process. The STERRAD 50 Sterilizer reports its status in three ways:

- **Monitor Screen (VGA Display)**—The display indicates the status of the unit at all times the unit is powered on. It also indicates the time remaining to cycle completion. When not in use, the screen saver engages, resulting in a blank display. Press any button to activate the display.
- **Paper printout**—A paper printout exits the printer after each cycle completion or cancellation. This is a record of the cycle parameters and may be kept for your records. The print should be completely black. Red print indicates a problem with the cycle. The printer is located on the lower right side of the unit. The paper advance button is on the printer door near the paper exit slot.
- **Beeps**—Beeps alert you when a cycle is complete, or a cancellation has occurred. A long beep indicates a complete cycle.

System Displays

This section is your guide for navigating the displays of the STERRAD 50 Sterilizer. Each display shows you the date and time at the bottom left of the screen, and the total number of cycles completed at the bottom right of the screen. At the right of the screen is a list of five functions, and to the right of these are corresponding buttons used to activate each function. The displays shown here are the only ones accessible to you. Your Field Service Engineer has access to a number of other displays that perform various tests and diagnostics on your system. These "Service Mode" displays should only be used by ASP trained and experienced service personnel.

Main Display

The main display of the STERRAD 50 Sterilizer is the starting point for all the functions you will be using. When you press the EXIT button on any subsequent display, you are returned to the main display. The right side of the display shows three buttons: START CYCLE, SYSTEM FUNCTIONS, and HELP. If the door is not closed and secured, the START CYCLE indication is not present.

✓ *Note: If the display is blank upon approaching the sterilizer, the screen saver is probably engaged. Press any button to activate the display.*

4 Day-to-Day Operation



Figure 3. Main Display. Ready to Use.

START

To begin the sterilization process be sure that the chamber has been properly loaded and that all necessary biological and chemical indicators are in place according to the instructions in the previous chapter. Make sure the door is closed and secure.

To start a cycle, do the following:

1. Press the START button. The display changes to show the progress and status of the cycle.

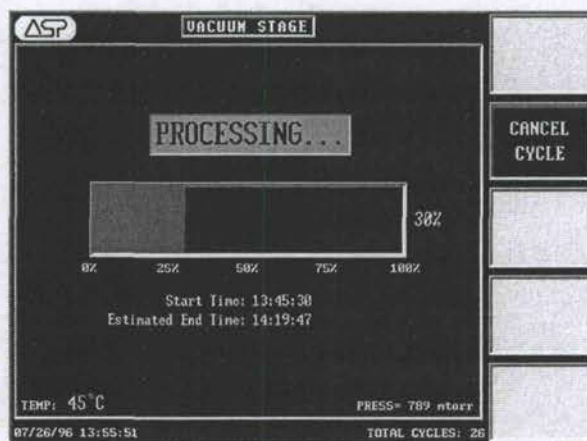


Figure 4. Cycle in process. Cancel is the only option available during the cycle.

The status bar at the top center of the display identifies the cycle stage. The graphic shows the cycle progress in percentage completed. Below this are the cycle start time, the estimated end time, and the chamber pressure and temperature. The right side of the display shows the CANCEL button.

HELP

Help is available for every display on the sterilizer. To get help, do the following:

1. Press the HELP button to view detailed information for the current display.
2. Press the EXIT HELP button to close the Help display.

4 Day-to-Day Operation

CANCEL

You can cancel a cycle at any time by pressing the CANCEL button, except during the final vent phase. The STERRAD 50 Sterilizer may also cancel a cycle if it detects a problem with the cycle.

To cancel a cycle, do the following:

1. Press the CANCEL button. When the sterilizer completes the cycle cancellation process, the main display reappears.

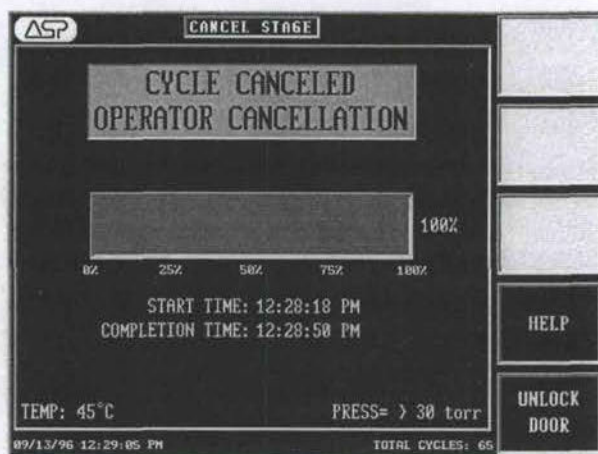


Figure 5. Display showing cancelled cycle information.

2. After the sterilizer has completed the cycle cancellation, you must press UNLOCK DOOR to release the door lock and then pull up on the handle to open the door and remove the sterilized items.

System Functions Display



Figure 6. Pressing SYSTEM FUNCTIONS displays this screen.

To access the system functions display, do the following:

1. Press the SYSTEM FUNCTIONS button. The right side of the display shows five buttons: DATE/TIME, CYCLE HISTORY, SYSTEM TOOLS, HELP, and EXIT.
2. Press the DATE/TIME button to open the Date/Time display to change date and time settings.
3. Press the CYCLE HISTORY button to access cycle history information.
4. Press the SYSTEM TOOLS button to open the System Tools display.
5. Press the HELP button to open the Help display.
6. Press the EXIT button to return to the main display.

4 Day-to-Day Operation

DATE/TIME

To change the date or time from the System Functions display, do the following:

✓ *Note: More detailed instructions on setting the date or time are shown in the Routine Maintenance chapter.*

1. Press the DATE/TIME button. The Date/Time display shows three fields: Date, Time, and Mode. The right side of the display shows five buttons: + (plus), - (minus), SELECT, HELP, and EXIT. Time can be displayed in a 24-hour or 12-hour format.

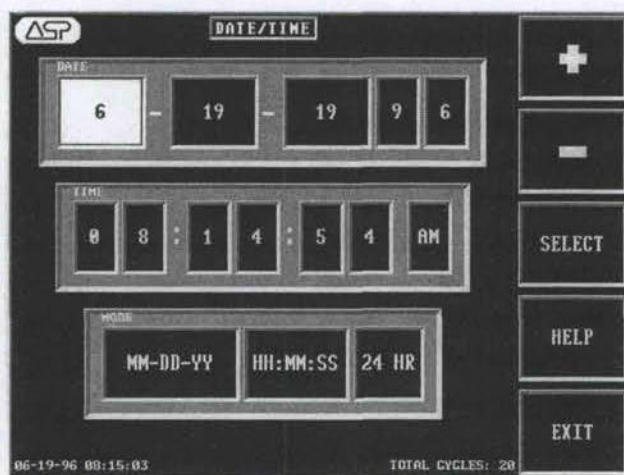


Figure 7. Use this display to change the date and/or the time.

2. Press the + or - buttons to change the highlighted character.
3. Press the SELECT button to move the cursor through the fields.
4. Press the HELP button to display the Help display for the current display.
5. Press the EXIT button to return to the main display.

CYCLE HISTORY

To review the cycle history from the System Functions display, do the following:

1. Press the CYCLE HISTORY button.

ASP

CYCLE HISTORY

DATE	START TIME	END TIME	STATUS
09/13/96	09:12:37 AM	09:59:29 AM	PROCESS COMPLETE
09/13/96	08:16:20 AM	09:03:26 AM	PROCESS COMPLETE
09/12/96	04:21:04 PM	05:07:56 PM	PROCESS COMPLETE
09/12/96	10:22:57 AM	11:09:56 AM	PROCESS COMPLETE
09/12/96	09:31:12 AM	10:18:24 AM	PROCESS COMPLETE
09/12/96	12:33:29 AM	01:20:25 AM	PROCESS COMPLETE
09/12/96	11:45:33 PM	12:32:29 AM	PROCESS COMPLETE
09/11/96	10:57:31 PM	11:44:33 PM	PROCESS COMPLETE
09/11/96	10:09:14 PM	10:56:31 PM	PROCESS COMPLETE
09/11/96	09:20:51 PM	10:08:14 PM	PROCESS COMPLETE
09/09/96	03:53:22 PM	04:40:01 PM	PROCESS COMPLETE
09/09/96	03:05:41 PM	03:52:22 PM	PROCESS COMPLETE
09/09/96	02:17:59 PM	03:04:41 PM	PROCESS COMPLETE
09/09/96	01:30:20 PM	02:16:59 PM	PROCESS COMPLETE
09/09/96	12:42:41 PM	01:29:20 PM	PROCESS COMPLETE
09/08/96	05:49:48 PM	06:36:28 PM	PROCESS COMPLETE
09/08/96	05:02:06 PM	05:48:48 PM	PROCESS COMPLETE
09/08/96	04:14:25 PM	05:01:06 PM	PROCESS COMPLETE
09/08/96	03:26:47 PM	04:13:25 PM	PROCESS COMPLETE
09/08/96	02:39:09 PM	03:25:47 PM	PROCESS COMPLETE
09/08/96	02:37:04 PM	02:30:45 PM	POWER INTERRUPTED
09/06/96	12:55:06 PM	01:41:46 PM	PROCESS COMPLETE

09/13/96 12:14:40 PM

TOTAL CYCLES: 65

↑

↓

OPEN

HELP

EXIT

Figure 8. CYCLE HISTORY display.

2. The Cycle History display contains information about the previous 1500 cycles. The display shows, from left to right: Date, Start Time, End Time, and Status of each cycle. The right side of the display shows five buttons: ↑ (up arrow), ↓ (down arrow), OPEN, HELP, and EXIT.
3. Press the ↑ or ↓ button to scroll to and highlight a cycle.
4. Press the OPEN button to see a more detailed history of a particular cycle. Press the PRINT button to obtain a printout of the cycle information.
5. Press the HELP button to open the Help display.
6. Press the EXIT button to return to the main display.

4 Day-to-Day Operation

To see a detailed history of the highlighted cycle from the Cycle History display, do the following:

1. Press the OPEN button. The top row of this display shows the Date, Start Time, End Time, Elapsed time, and Cycle number. Subsequent rows show the following information:
 - A list of cycle stages, Start time, End time, Total time, and Pressure and Temperature for each stage.
 - The Cycle Status field displays the final status of the cycle.
 - The Total Cycles, number Passed, and the number Failed.
 - The right side of the display shows four buttons: CLOSE, PRINT, HELP, and EXIT.
2. Press the CLOSE button to return to the original Cycle History display.
3. Press the PRINT button to print a cycle record, according to facility policy.
4. Press the HELP button to open the Help display.
5. Press the EXIT button to return to the main display.

SYSTEM TOOLS

To use the System Tools from the System Functions display, do the following:

1. Press the SYSTEM TOOLS button. The right side of the display shows four buttons: CONFIGURE, CASSETTE FUNCTIONS, HELP, and EXIT.



Figure 9. Press **CONFIGURE** to gain access to the ID String Editor.

2. Press the **CONFIGURE** button to open a display that lets you use the ID String Editor.
3. Press the **CASSETTE FUNCTIONS** button.
4. Press the **HELP** button to open the Help display.
5. Press the **EXIT** button to return to the main display.

ID STRING EDITOR

Use the ID String Editor to personalize the sterilizer. This is normally done upon initial installation and set up, but is accessible by you. From this display, you can specifically identify each STERRAD 50 Sterilizer by location or other specific information. This information is printed by the sterilizer on completion of a cycle.

To use the ID String Editor from the System Tools display, do the following:

1. Press the **CONFIGURE** button.
2. The right side of this new display shows three buttons: **ID STRING EDITOR**, **HELP**, and **EXIT**.

4 Day-to-Day Operation



Figure 10. Press ID STRING EDITOR, HELP or EXIT from this display.

3. Press the ID STRING EDITOR button to open the ID String Editor display. The ID String Editor display has two fields. The first field displays only the currently highlighted character. The second field displays the entire ID string or name. The right side of the display shows five buttons: ↑ (up arrow), ↓ (down arrow), SELECT, HELP, and EXIT.

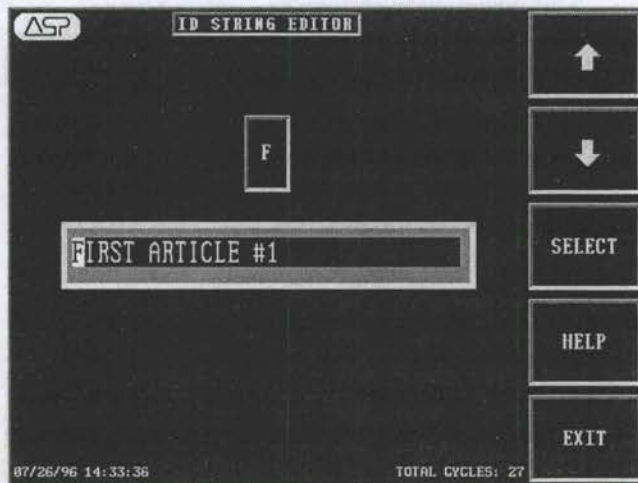


Figure 11. You may use your own identification in this field.

4. Press the ↑ or ↓ button to change the highlighted character.
5. Press the SELECT button to move through and highlight the characters.
6. Press the HELP button to open the help display.
7. Press the EXIT button to return to the main display.

Cassette Functions Tools

The cassette function tools, available on newer systems and systems with upgraded software, allow you to control some of the actions of the cassette. The Cassette Functions display shows EJECT CASSETTE, INDEX CASSETTE (not available on all systems), and RESET BARCODE. Each of these features is described below.

To access the cassette function tools, do the following:

1. From the main menu press SYSTEM FUNCTIONS.
2. From the System Functions display press SYSTEM TOOLS.
3. From the System Tools display press CASSETTE FUNCTIONS.

4 Day-to-Day Operation



Figure 12. CASSETTE FUNCTIONS display. View this display from the system tools display. Press CASSETTE FUNCTIONS to view the next display.

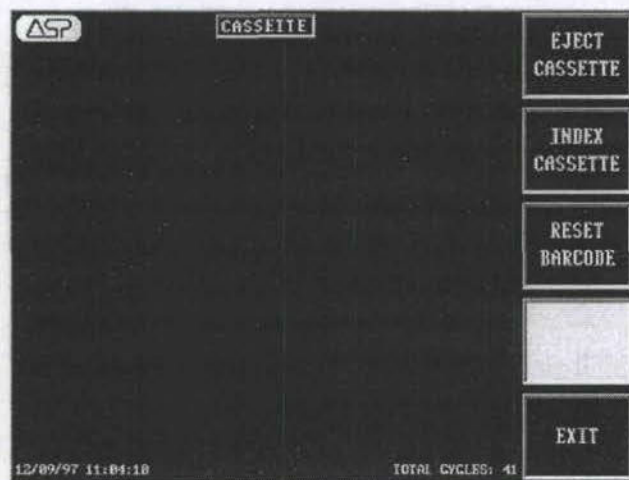


Figure 13. This display is shown when you press CASSETTE FUNCTIONS. INDEX CASSETTE is not available on all systems.

Eject Cassette

After inserting a cassette, you may see the message *Cassette System Interrupted*. At this time the cassette is still in the sterilizer and needs to be removed. Do the following to remove the cassette:

1. Access CASSETTE FUNCTIONS as shown above. Press EJECT CASSETTE. The following display appears and the cassette is ejected into the sleeve. Insert a new, valid cassette. The ejected cassette can NOT be reused. The cassette barcode is not readable after it has been inserted and removed from the sterilizer.

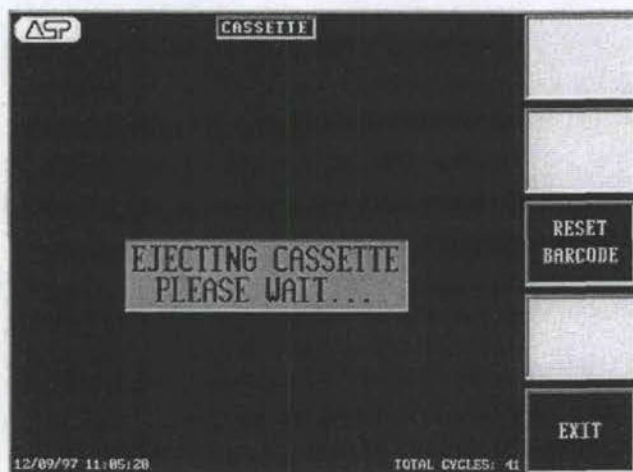


Figure 14. The cassette is being ejected. EJECT CASSETTE has been pressed on the cassette functions display.

✓**Note:** If you need to remove a cassette from the sterilizer, use this procedure. Do not try to remove cassettes during a cycle.

4 Day-to-Day Operation

Index Cassette

✓ *Note: This feature is not available on all systems.*

CAUTION: *Manually indexing the cassette results in the loss of at least one cycle capacity of the cassette.*

If you suspect that a cassette failed to index properly (advance to the next cell) after injection or a cassette has gotten stuck in the system, do the following:

1. Access CASSETTE FUNCTIONS as shown previously. Press INDEX CASSETTE. The following display appears and the cassette advances to the next available cell.

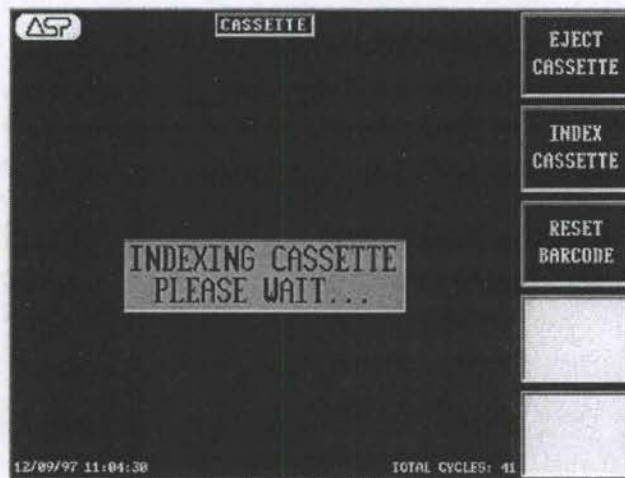


Figure 15. Pressing INDEX CASSETTE advances the cassette to the next available cell.

2. After indexing has been successful, the system is available to run a cycle.
3. If indexing is not successful, try ejecting the cassette. If this fails, please call your ASP Service Representative for technical service or to schedule a repair procedure.

Reset Barcode

The system stores barcode information in a file called a buffer. On rare occasions this buffer may retain too much data and produce a false error. That is, it displays a barcode error when there is, in fact, nothing wrong with the barcode on your cassette. If you have inserted two or more new cassettes and received barcode error messages, do the following:

1. Access CASSETTE FUNCTIONS as shown previously. Press RESET BARCODE. This clears the barcode reader transmission buffer.



Figure 16. Press RESET BARCODE to clear the buffer of excess data.

2. If the reset is successful, you may run a cycle as usual.
3. If the reset is unsuccessful, then there is a problem within the system. Please call your ASP Service Representative for technical service or to schedule a repair procedure.

4 Day-to-Day Operation



Figure 17. If the reset is unsuccessful, you must schedule a repair procedure.

Preparing the Load

Proper preparation of trays, pouches, and instruments can minimize or prevent cycle cancellation due to load-related problems. More information on load preparation is found in "Chapter 3. Preparing Items To Be Sterilized."

- Arrange the items in a tray to ensure that the hydrogen peroxide and plasma can surround them. Do not stack trays.
- Place peel pouches on edge, if possible. Arrange them so that the transparent side of a pouch faces the opaque side of the next pouch.
- Do not allow any item to touch the walls or door of the sterilization chamber or electrode.
- Provide at least 25 mm (1 inch) of space between the electrode the load.
- Place the STERRAD CycleSure Biological Indicator or other ASP-approved biological indicator in the sterilization chamber.

CAUTION: *Metal objects must not come into contact with the chamber walls, door or electrode. Contact with the walls, door or electrode can cause a cycle cancellation and/or damage the items or the sterilizer.*

Biological Indicators

Biological indicators help you to assure that your sterilizer is operating correctly. Confirming that sterilizing conditions were present during a cycle is an important part of the sterilization process. Frequency of biological testing should be at least once per day or in accordance with your hospital policy.

- Contact your ASP representative regarding biologicals specifically designed for use in STERRAD Sterilizers.

ASP biological indicators contain microorganisms that are known to be resistant to the sterilization process and are the best way to verify proper processing. The biological indicator should be placed at the back of the chamber, on the bottom shelf with the opening facing the back of the chamber. Review the instructions that are included with the biological indicators for proper use.

The following charts detail the transfer process and a flow chart showing the entire biological indicator procedure for both ASP-approved biological indicators.

- ✓ *Note: Should a cancellation occur when a biological indicator is in the chamber, it should be discarded and a new biological indicator should be used when starting the next cycle.*

BI Transfer Process for STERRAD® BI Test Pack

Set Up

Do:

- Clean the transfer area with sporidical solution.
- Have 2 sterile forceps (individually wrapped).
- Use a new, sterile catalase vial.
- Label 4 TSB tubes (processed BI, positive control, catalase, and TSB).
- Have an incubator set at 30-35° C.

Don't:

- Use damaged or leaking test tubes.
- Re-use the catalase vial.
- Forget to label each tube correctly.

Transfer

Do:

- Have a trained individual perform the transfer within 5 minutes of cycle completion.
- Add a drop of catalase to all tubes except the tube labeled "TSB" 15 minutes before cycle completion.
- Check to see if the CI of the processed BIIP changed color.
- Unscrew lids on all 4 test tubes.
- Rest lids on the tubes.
- Transfer the processed BI strip to the labeled tube first.
- Use different sterile forceps to transfer the positive control.
- If BI strip is dropped on the counter, make a note of it.

Don't:

- Place test tube lids on the counter.
- Allow skin contact with any components.
- Use the same forceps to transfer the processed BI and the positive control.
- Perform transfer in a turbulent area (people traffic, AC vents, etc.).
- Wait more than 5 minutes to transfer; hydrogen peroxide residual activity will inactivate spores.

Incubation

Do:

- Loosen test tube lids 1/2 turn for oxygen.
- Incubate test tubes at 30-35° C.
- Incubate for at least 48 hours prior to reading results.

Don't:

- Over tighten lids. Spores are aerobic and need oxygen to grow.
- Forget to check temperature range of incubator. It should be 30-35° C.

Interpretation of Results

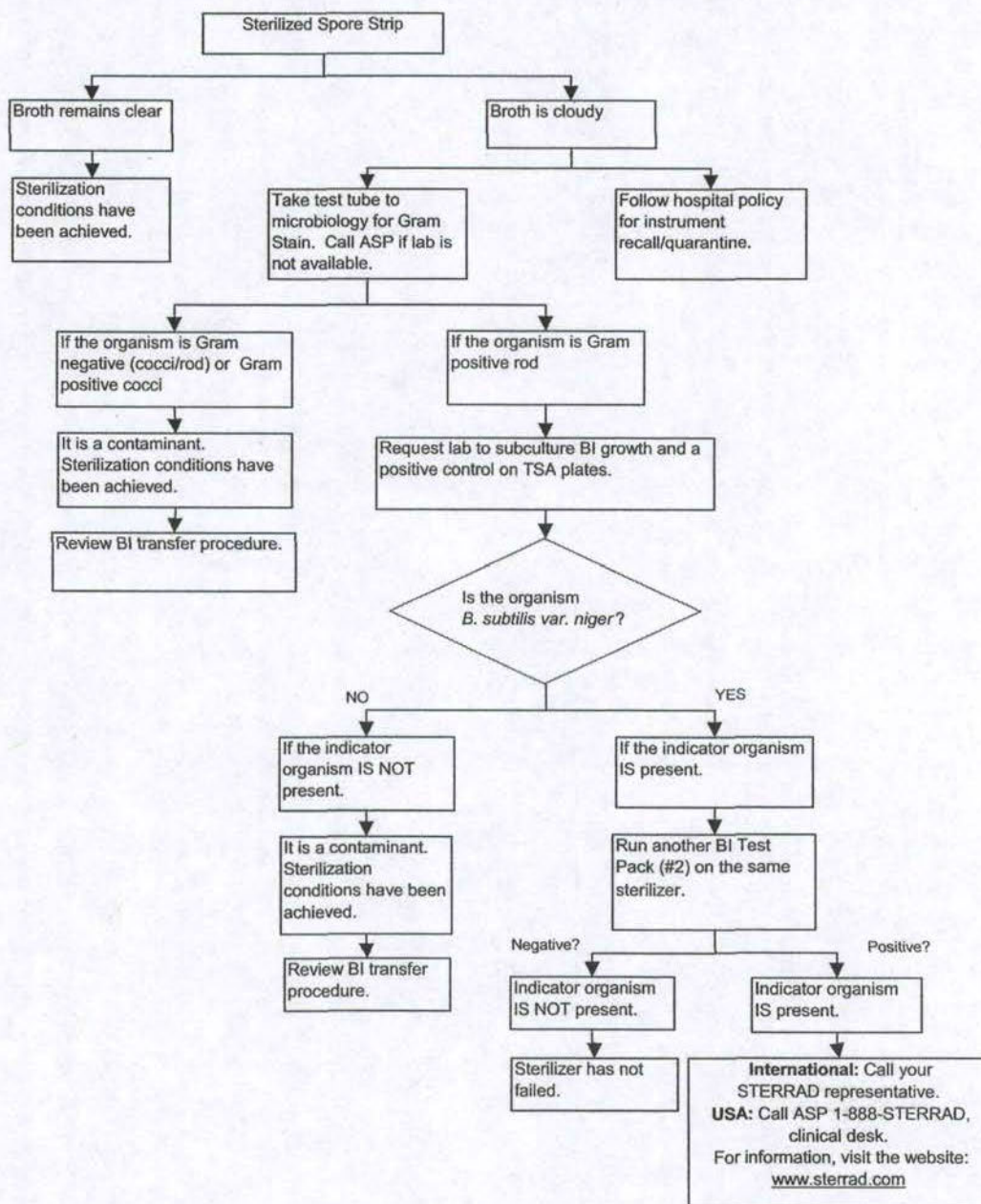
Desired Results:

- Processed BI strip: no growth.
- Control BI strip: growth (turbidity and/or orange color particles).
- Catalase control: no growth.
- TSB control: no growth.

Other Results:

- Processed BI strip: growth (turbidity and/or orange color) (See BI Flowchart.)
- Control BI strip: no growth
 - » lid too tight
 - » incubator temperature out of range.
 - » strip inactivated during storage.
 - » media does not support growth.
- Catalase control: growth (turbidity)
 - » contaminated catalase.
 - » no aseptic transfer.
- TSB control: growth (turbidity)
 - » contaminated media.

Biological Monitoring Results-Biological Indicator Test Pack



4 Day-to-Day Operation

Process Flow For CycleSure™ Biological Indicator

Set Up

Do:

- Label the BI to be processed appropriately.
- Label positive and negative controls.
- Package BI in a manner consistent with items being sterilized.
- Place BI in the most challenging area for sterilizer to reach.
- Inspect BIs for any defects before using; e.g., cracked media ampoule.
- Have an incubator set at 55-60° C.

Don't:

- Forget to label CycleSure BIs correctly.
- Press the caps down before processing BIs.

Incubation

Do:

- Activate CycleSure™ BI within 5 minutes after cycle completion.
- Check the chemical indicator disc for color change from red to yellow.
- Press the cap down until firmly seated on top of vial.
- Crush media ampoule using the tube crusher.
- Keep vial in vertical position after media ampoule has been crushed.
- Use Controls:
 - » Positive control: crush an unprocessed CycleSure BI.
 - » Negative Control: An unprocessed and uncushed BI.
 - » Incubate processed BI and controls at 55-60° C.
 - » Incubate for at least 48 hours (up to 7 days) prior to reading results.

Don't:

- Forget to check temperature range of incubator. It should be between 55-60° C.
- Forget to crush media ampoule for processed BI and positive control.
- Forget to press caps down on BIs before incubating to prevent dehydration.

Interpretation of Results

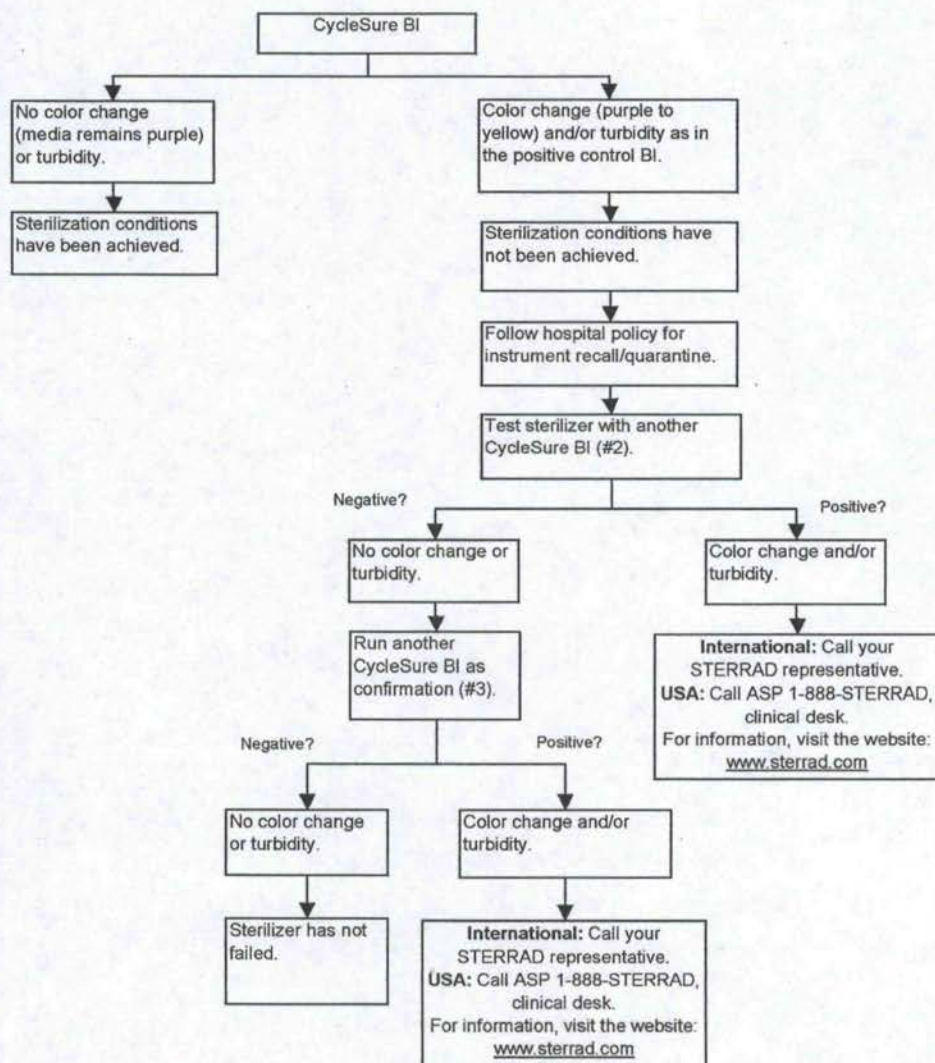
Desired Results:

- Observe for color change in the processed BI and controls.
- Processed BI: no growth (no color change, media remains purple).
- Positive Control: growth (color change in media from purple to yellow).
- Negative Control: no growth (media shall remain purple).

Other Results:

- Processed BI: growth (color change in media from purple to yellow). See CycleSure™ BI flow chart.
- Positive Control: no growth (no color change)
 - » Incubator temperature out of range.
 - » BI inactivated during storage.
 - » media does not support growth.
- Negative Control: growth (color change in media from purple to yellow)
 - » contaminated media ampoule.

Biological Monitoring Results-CycleSure™



Chemical Indicators

STERRAD Chemical Indicator Strips and STERRAD Chemical Indicator Tape offer additional ways to verify processing in the sterilization cycle. They should be used in addition to, not in place of, the biological indicator. STERRAD Chemical Indicator Strips and STERRAD Chemical Indicator Tape *do not* indicate sterilization; they only indicate that the indicator has been exposed to the hydrogen peroxide. The color of the indicator strips and tape changes from red to yellow (or lighter) when exposed to hydrogen peroxide vapor.

✓ *Note: Use only STERRAD Chemical Indicator Tape, and/or STERRAD Chemical Indicator Strips. Do not use indicators designed for other sterilization processes.*

Using Chemical Indicator Strips

Place STERRAD Chemical Indicator Strips in trays and pouches to show exposure to hydrogen peroxide during the sterilization cycle. Please refer to the *Instructions for Use* included with the STERRAD Chemical Indicator Strip for more information.

Using Chemical Indicator Tape

Chemical Indicator Tape should be used to secure polypropylene sterilization wrap around the Instrument Tray.

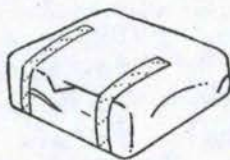


Figure 18. STERRAD® Chemical Indicator Tape should be used to secure the polypropylene wrap around each instrument tray.

Please refer to the *Instructions for Use* included with the STERRAD Chemical Indicator Tape for more information.

Loading the Sterilization Chamber

- Arrange the items in the trays to ensure that the hydrogen peroxide and plasma can surround them. Do not stack trays within trays.
- Trays must be placed flat on shelf.
- Place peel pouches on edge, if possible.
- Do not allow any metal items to touch the walls, door, or electrode of the sterilization chamber or electrode.
- Provide at least 25 mm of space between the electrode and the load.

Inserting a Cassette

The STERRAD 50 Sterilizer uses hydrogen peroxide, contained in special cassettes, to sterilize items placed into the sterilization chamber. Each STERRAD 50 Cassette provides enough hydrogen peroxide for 5 cycles. The message display of the STERRAD 50 Sterilizer notifies you when a new cassette is needed.

WARNING! STERRAD 50 CASSETTES CONTAIN CONCENTRATED HYDROGEN PEROXIDE, A STRONG OXIDIZER. CONCENTRATED HYDROGEN PEROXIDE IS CORROSIVE TO SKIN, EYES, NOSE, THROAT, LUNGS, AND GASTROINTESTINAL TRACT. DIRECT CONTACT WITH THE SKIN CAN CAUSE SEVERE IRRITATION. IF SKIN CONTACT OCCURS, IMMEDIATELY FLUSH WITH LARGE AMOUNTS OF WATER. IF SYMPTOMS ARE SEVERE OR PERSIST, CONSULT A PHYSICIAN IMMEDIATELY.

DIRECT CONTACT WITH EYES CAN CAUSE IRREVERSIBLE TISSUE DAMAGE. IF EYE CONTACT OCCURS, IMMEDIATELY FLUSH WITH LARGE AMOUNTS OF WATER AND IMMEDIATELY CONSULT A PHYSICIAN.

4 Day-to-Day Operation

INHALATION OF VAPOR OR MIST CAN CAUSE SEVERE IRRITATION OF LUNGS, THROAT, AND NOSE. IF INHALATION OCCURS, MOVE TO FRESH AIR AND CONSULT A PHYSICIAN IMMEDIATELY.

INGESTION CAN PRODUCE CORROSION THAT MAY BE LIFE-THREATENING. IF SWALLOWED, DRINK PLENTY OF WATER IMMEDIATELY TO DILUTE. DO NOT INDUCE VOMITING. CONSULT A PHYSICIAN.



Figure 19. If skin contact occurs, immediately flush the area with water.

WARNING! DO NOT REMOVE THE PLASTIC WRAPPER FROM THE CASSETTE PACKAGE IF THE INDICATOR STRIP IS RED. RED INDICATES DAMAGE. CALL YOUR ASP REPRESENTATIVE FOR CREDIT.

To insert a cassette, do the following:

1. Confirm that the sterilizer display indicates that a new cassette is needed.
2. Confirm that the chemical indicator strip on the cassette sleeve is NOT red; red indicates that the cassette may be damaged.
3. Confirm that the cassette expiration date has not passed.

✓Note: The system considers the cassette expired 10 days after insertion regardless of the printed expiration date. The cassette is ejected at that time.

4. Remove the plastic wrapping from the cassette sleeve. Do NOT remove the cassette from the remaining heavy paper sleeve.

✓ *Note: Do not remove the plastic wrapping until ready to insert the cassette.*

5. Orient the arrow so that the top of the cassette sleeve is pointing away from you.
6. Hold the paper sleeve by its edges and insert it into the sterilizer.

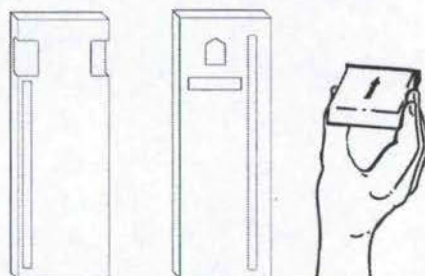


Figure 20. Note the orientation of the arrow on the heavy paper sleeve. Insert the entire cassette sleeve into the sterilizer.

7. Push the paper sleeve in firmly until it can go no further. If positioned properly, the cassette snaps into place.
8. If the paper sleeve is not pushed in all the way, the monitor continues to read INSERT CASSETTE.
9. If the paper sleeve is properly positioned, the cassette is automatically accepted and positioned for use by the sterilizer. The display reads CASSETTE ACCEPTED.
10. If the cassette is not accepted because the barcode cannot be read or the cassette has expired, PLEASE REMOVE CASSETTE is displayed. Should this occur, remove that cassette and insert a valid one.

✓ *Note: The system microprocessor monitors the status of the cassette and informs the operator when the cassette is empty or expired. Empty or expired cassettes must be replaced prior to starting the cycle.*

4 Day-to-Day Operation

WARNING! DO NOT REMOVE USED CASSETTES FROM THE PROTECTIVE CARDBOARD SLEEVE. DISPOSE OF THE CASSETTE INSIDE THE PROTECTIVE SLEEVE FOLLOWING HOSPITAL PROCEDURES OR IN NORMAL HOSPITAL WASTE. IF THE RETAINER HOLDING THE PLASTIC CASSETTE IN THE CARDBOARD SLEEVE IS DAMAGED AND THE USED CASSETTE FALLS OUT, WEAR LATEX, PVC (VINYL) OR NITRILE GLOVES TO PLACE THE PLASTIC CASSETTE BACK IN THE ORIGINAL SLEEVE. DISCARD THE CASSETTE INSIDE THE SLEEVE, FOLLOWING HOSPITAL PROCEDURES OR IN NORMAL HOSPITAL WASTE.

Please refer to the *Instructions for Use* included with the STERRAD 50 Cassette for more information.

Sterilization Cycles

Starting a Cycle

✓ *Note: Make sure you read, understand, and follow "Chapter 2. For Your Safety," and the sections in this chapter on preparing the load, and using biological and chemical indicators before starting a cycle.*

In order to start a cycle, and to perform many other functions of the STERRAD 50 Sterilizer, you must press the appropriate button next to the display. The button labels are outlined on the display and change according to the type of display shown.

After the load has been properly placed into the sterilizer, and the biological and chemical indicators are in place, you are ready to start the cycle.

1. Close the door to the sterilization chamber by lifting up on the handle and pulling the door upward until the door is closed. Press the handle down to secure the door.
2. Press the START button.

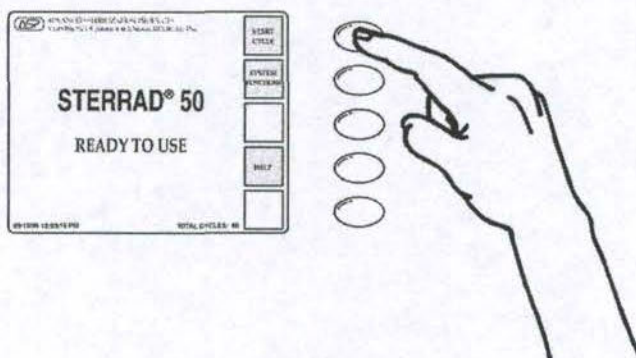


Figure 21. Press the START button to start a cycle.

3. The door locks and the cycle begins. If all cycle parameters stay within their limits, the cycle is completed in approximately 45 minutes.

Watching a Cycle

You can monitor the progress of a cycle by watching the display; it indicates the phase of the cycle and certain process parameters. A long beep signals that the cycle is complete.

The display indicates the status of the unit at all times: the current stage of the sterilization cycle, the temperature in the chamber, the pressure in the chamber, the cycle start time and the cycle estimated end time. Each load goes through eight consecutive stages: vacuum, injection, diffusion, plasma, injection, diffusion, plasma, and vent. These stages always follow the same order, but some take longer than others.

4 Day-to-Day Operation

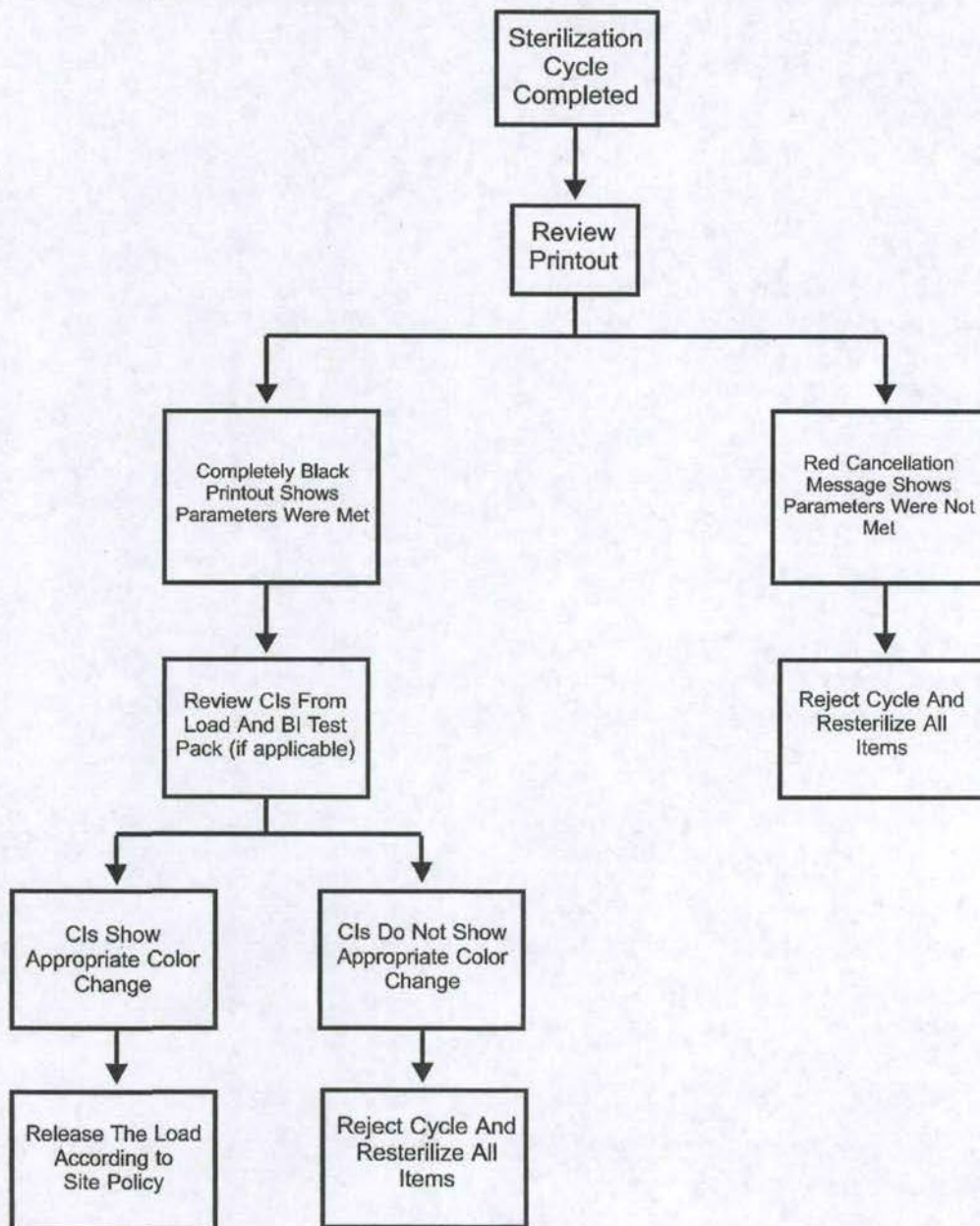
Order	Stage	Duration (Approx.)
1	Vacuum	20 minutes
2	Injection	6 minutes
3	Diffusion	2 minutes
4	Plasma	4 minutes
5	Injection	6 minutes
6	Diffusion	2 minutes
7	Plasma	4 minutes
8	Vent	1 minute

Completing a Cycle

Cycle completion is signaled in four ways:

- A long beep sounds.
- PROCESS COMPLETE is displayed on the monitor.
- OPEN DOOR TO REMOVE LOAD is displayed on the monitor.
- The paper printout shows the process parameters (in black ink only; red ink indicates a problem).

Cycle Completion Flow Chart



4 Day-to-Day Operation

Canceling a Cycle

Manual Cancellation

You can cancel a cycle at any time by pressing the CANCEL button, except during the final vent phase.

To manually cancel a cycle, do the following:

1. Press the CANCEL button.
 - Ten beeps sound, and the message display shows CYCLE CANCELED/OPERATOR CANCELLATION.
 - A paper printout exits the printer with a message in red ink.
 - The sterilizer automatically completes the cancellation process (which includes a short plasma stage during most phases of the process).
 - The display indicates when cancellation is complete.

Loads from canceled cycles should be repackaged using new polypropylene wrap, STERRAD Chemical Indicator Strips, and STERRAD Chemical Indicator Tape. If a STERRAD Biological Indicator was used in the canceled load, it should be discarded and a new one should be placed in the chamber before starting the new cycle.

WARNING! IF THERE IS A CYCLE CANCELLATION AND THE ITEMS IN THE LOAD APPEAR WET, CONCENTRATED HYDROGEN PEROXIDE MAY BE PRESENT. WEAR LATEX, PVC (VINYL) OR NITRILE GLOVES WHILE REMOVING THE ITEMS FROM THE CHAMBER, AND TO WIPE OFF THE ITEMS WITH A DAMP CLOTH.

Automatic Cancellation

The STERRAD 50 Sterilizer may also cancel a cycle if it detects a problem with the cycle. If the sterilizer control system cancels a cycle, the display indicates when the cancellation process is complete. As with manual cancellation (above), the load should be repackaged using new polypropylene wraps, biological indicators, chemical indicators, etc. Note the messages on the display and on the paper printout, and refer to "Chapter 6. Troubleshooting" for more information.

Unloading and Handling

Items processed by the STERRAD 50 Sterilizer can be used as soon as the sterilization cycle is complete according to facility procedures. No additional time for aeration is required.

To unload the chamber:

1. Press UNLOCK DOOR to release the locking mechanism.
2. Lift the handle of the door of the STERRAD 50 Sterilizer, then pull the door towards you and downward to open the sterilizer.
3. Remove chamber contents.
4. Close the door and press down on the handle latch to secure the door.
5. After ensuring that the STERRAD Chemical Indicators exhibit the correct color change, the sterilized items are ready for immediate use, following facility policies and procedures.

Power ON-OFF Switch/Rebooting the System

The Power ON-OFF switch is located at the back of the sterilizer. Flip the switch to the OFF position to shut off power to the sterilizer. Turning the power switch to ON returns power to the sterilizer and causes the computer in the sterilizer to reload the software control program automatically; this action reboots the sterilizer. Rebooting is used in certain troubleshooting procedures. The display indicates that the system is READY TO USE.

Chapter 5. Routine Maintenance

In this chapter . . .

- *maintaining the printer*
- *resetting the date and time*
- *cleaning the sterilizer*
- *cleaning the injector valve vaporizer bowl and deflectors*

5 Routine Maintenance

Overview

This section is your guide to the maintenance procedures for the STERRAD® 50 Sterilizer. Contact ASP Technical Service for guidance on all other maintenance procedures.

WARNING! ONLY ASP-TRAINED TECHNICIANS SHOULD REPAIR OR ADJUST THIS UNIT. REPAIRS AND ADJUSTMENTS SHOULD ONLY BE ATTEMPTED BY EXPERIENCED TECHNICIANS WHO ARE FULLY TRAINED TO MAINTAIN AND REPAIR THE STERRAD 50 STERILIZER.

USE OF UNAUTHORIZED PARTS MAY BE DANGEROUS AND WILL VOID THE WARRANTY. USE OF UNAUTHORIZED PARTS FOR MAINTENANCE OR REPAIR COULD CAUSE PERSONAL INJURY, RESULT IN COSTLY DAMAGE OR UNIT MALFUNCTION, AND WILL VOID THE WARRANTY.

Maintaining the Printer

The printer requires that the ribbon cartridge be replaced whenever the print becomes too light to read easily. The paper should be changed when the colored bars begin to appear on the paper. This indicates the paper supply is running low. The illustration below shows the printer installed on the printer door. Your system may or may not have this configuration. The ribbon cartridge and paper changing routines shown in this chapter are the same regardless of the location of the printer.

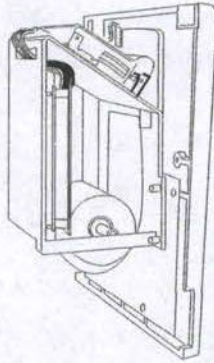


Figure 22. Printer mounted on printer door.

Replacing the Printer Ribbon Cartridge

To replace a printer ribbon cartridge do the following:

1. Open the right service door by pressing on the corner to release the door. Pull the printer assembly drawer forward (if present).

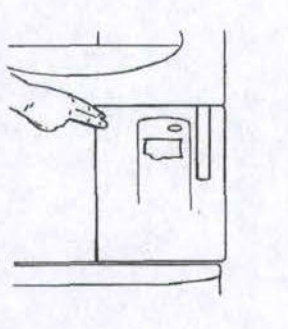


Figure 23. Press the corner to open the service door.

2. Firmly, but carefully, pull on the right side of the used ribbon cartridge, as indicated by the arrow on the cartridge. Remove the used cartridge and discard.

5 Routine Maintenance

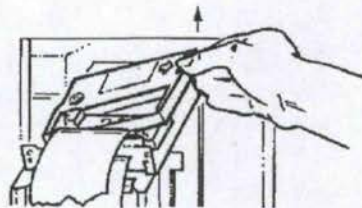


Figure 24. Removing the used ribbon cartridge.

3. Insert a new cartridge by aligning the left side of the cartridge with the bracket in the printer. Push on the right side of the cartridge to snap it into place.

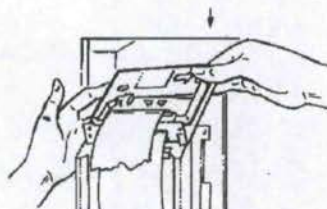


Figure 25. Inserting a new ribbon cartridge.

4. Turn the knob on the cartridge clockwise to remove any slack from the ribbon.

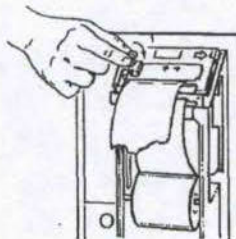


Figure 26. Turn the knob on the cartridge to remove slack from the ribbon.

5. Push the printer assembly drawer back into place. Make sure the printer paper feeds through the printer paper slot in the service door. Close the service door.

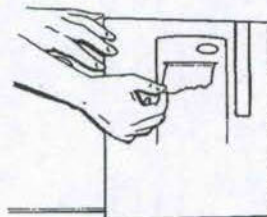


Figure 27. Feed the printer paper through the slot in the printer service door.

5 Routine Maintenance

Replacing the Printer Paper

To replace the paper roll do the following:

1. Open the right service door and pull printer assembly drawer forward. (Not done on systems with the printer mounted on the door.)



Figure 28. Press the corner to open the service door.

2. Remove the empty paper core and discard the core.
3. Place a new paper roll into position so that the paper feeds from the back of the roll.

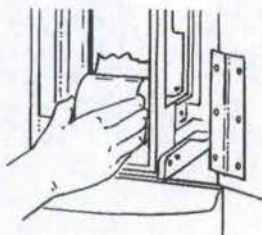


Figure 29. Place a new paper roll into the printer.

4. Feed the edge of the paper under the gray metal bar located in front of the printer cartridge and into the slot behind the printer. Push up gently on the paper and press PAPER ADVANCE until the mechanism begins to pull the paper. Continue pressing PAPER ADVANCE until about 150 to 160 mm (about 6 inches) of paper exits the printer cartridge.

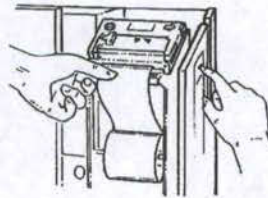


Figure 30. Advance the paper through the printer mechanism and the ribbon cartridge.

5. Make sure the printer paper feeds through the slot in the printer door. Close the door.

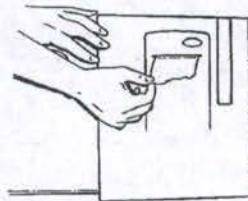


Figure 31. Feed the printer paper through the slot in the printer door.

Resetting the Date and Time

The date and time are set by your ASP service representative at installation. You can change these settings at any time to conform to local standards.

To change the date, do the following:

1. Press SYSTEM FUNCTIONS, as indicated on the display, then press DATE/TIME.

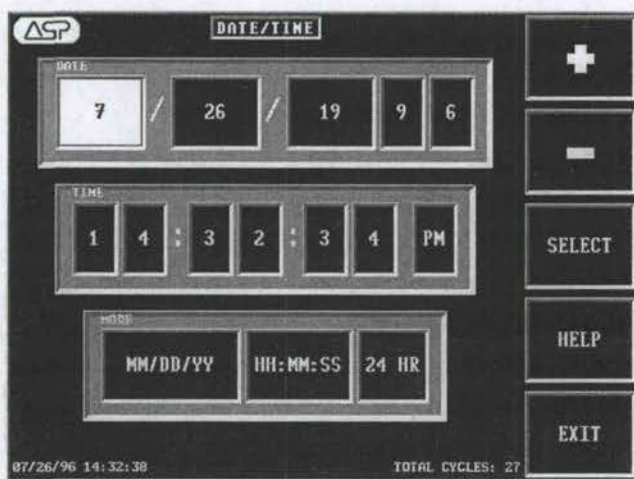


Figure 32. Date/Time Display

2. Press SELECT until the DATE box inside the mode block is lit, then press + (plus) or - (minus) until the desired date format appears in the date box. Note that the date style in the lower left corner changes as you change the mode.
3. Press SELECT until the month, day, or year inside the date block is lit, then press + or - until the desired number appears.
4. To accept all current settings and to exit this mode, press EXIT.

To change the time, do the following:

1. Press SYSTEM FUNCTIONS, as indicated on the display, then press DATE/TIME.

2. Press SELECT until the TIME box inside the mode block is lit, then press + or – until the desired time format appears in the time box. Note that the time style in the lower left corner changes as you change the mode.
3. Press SELECT until the 12/24 HR box inside the mode block is lit, then press + or – until the desired format appears in the box.
4. Press SELECT until the hour, minute, second or AM/PM box in the time block is lit, then press + or – until the desired number appears in the box.
5. To accept all current settings and to exit this mode, press EXIT.

Cleaning the STERRAD[®] 50 Sterilizer

The outside surfaces of the sterilizer can be cleaned with a mild detergent. The inside of the sterilization chamber does not normally require cleaning. The chamber door and the chamber should not be cleaned with an abrasive, such as a wire brush or steel wool. If you have any questions regarding cleaning the STERRAD 50 Sterilizer, call your ASP representative.

CAUTION: *Do not clean the chamber door area with abrasives. The sterilization chamber uses an O-ring vacuum seal to maintain a vacuum in the chamber. Never use rough cleaning tools, such as a wire brush or steel wool, on the door housing or chamber assembly. This could damage the seal.*

Cleaning the Deflector and Injector Valve Vaporizer Bowl

Your system has one of two types of deflectors: a deflector attached to the vaporizer bowl, or a deflector plate fitted into the electrode (also called a “vaporizer plate.”) To clean the injector valve vaporizer bowl and deflectors, do the following:

1. Wearing latex, PVC (vinyl), or nitrile gloves and eye protection, remove the attached deflector by turning the locking nut counterclockwise. If your system has the deflector plate, remove it by slightly pinching the sides and pulling down on the plate to remove it.

5 Routine Maintenance

2. Clean the exterior surface of the bowl and both sides of the attached deflector by wiping them with a clean, damp cloth. Rinse the deflector plate under running water. Dry it thoroughly.

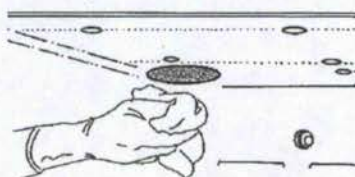


Figure 33. Clean the exterior surface of the bowl.

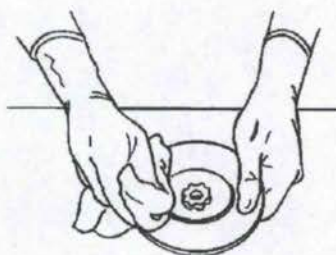


Figure 34. Cleaning the Attached Deflector.

3. Replace the attached deflector by turning the nut clockwise.
4. Replace the deflector plate by placing it diagonally in the square opening of the electrode. The bowl faces downward. Rotate it 1/8 turn until the oval wings seat on top of the electrode and the top lip is against the inside of the electrode. Move the plate backwards or forwards until you feel the vertical lip stop against the edge of the electrode.

CAUTION: Always reattach the deflector and reinstall the deflector plate. The sterilization cycle will not process correctly without the deflector.

Chapter 6.

Troubleshooting

In this chapter . . .

- *system message table in alphabetical order*

Overview

The STERRAD® 50 Sterilizer is a relatively trouble-free device, requiring only routine maintenance and care in load preparation to help prevent system cancellations.

Proper preparation of the load can help to ensure a minimal amount of cycle cancellations. Be sure you read, understand and follow all the safety procedures in Chapter 2 and the load preparation procedures in Chapter 3.

WARNING! YOU MUST WEAR LATEX, PVC (VINYL) OR NITRILE GLOVES WHEN REMOVING OR REINSERTING THE LOAD BECAUSE OF A CANCELED CYCLE.

Message Table

The messages in this table are in alphabetical order. You may receive similar messages during different stages of the system cycle. The action you are to take is usually the same regardless of the cycle stage. Also, some messages may end with slightly different wording than shown in the message table; this does not affect your handling of the message. Pressing HELP when a message is received provides you with more detailed instruction on resolving the system message.

Many system messages are the result of problems with the materials in the load. If you received one of these types of messages, be sure to inspect the load, and repackage if necessary. Be sure to replace all cycle indicators and biological indicators if they are being used. Remember, you can always press HELP for more information.

Displayed Message	Printed Message	Action
CASSETTE ACCEPTED	No printout.	Cassette is of the correct type and date, and is positioned correctly.
CASSETTE DID NOT INDEX	No printout.	Cassette did not successfully move to the next cell. Remove the cassette and insert a new one. If the message persists, call your ASP Service Representative.
CASSETTE NOT DETECTED	No printout.	Remove the cassette. Reinsert the same cassette or a new one. If the message persists, call your ASP Service Representative.
CASSETTE OUT-OF-DATE PLEASE REMOVE CASSETTE	Cassette out of date Cassette Exp _____(Date)	Ten days have passed since the cassette was inserted into the sterilizer and it is assumed to have expired. Insert a new cassette, or if you know that the cassette has NOT expired, press HELP when this message appears and follow the instructions.
CASSETTE SYSTEM INTERRUPTED	No printout.	Call your ASP Service Representative.
CASSETTE VERIFICATION UNSUCCESSFUL PLEASE REMOVE CASSETTE	Verification Unsuccessful Refer To Help Screen	The barcode cannot be read. Press HELP for more information or call your ASP Service Representative.
CYCLE CANCELED [may show any cycle canceled message] PLEASE WAIT... 10 MIN	[Printout May Show Any Cycle Canceled Message.] Please Inspect Load Carefully Refer To Help Screen	The instruments may have contained too much moisture before they were placed in the sterilizer. WARNING! WEAR LATEX, PVC (VINYL) OR NITRILE GLOVES WHEN REMOVING THE LOAD FROM THE CHAMBER AND WHILE CHECKING ITEMS FOR MOISTURE. Press HELP for more information or call your ASP Service Representative.

6 Troubleshooting

Displayed Message	Printed Message	Action
CYCLE CANCELED INJECTION SYSTEM INTERRUPTED PLEASE WAIT... 10 MIN	Cycle Canceled Injection System Interrupted Call ASP Technical Service	Call your ASP Service Representative.
CYCLE CANCELED INSUFFICIENT PLASMA PRESSURE PLEASE WAIT... 10 MIN.	Cycle Canceled Insufficient Plasma Pressure Refer To Help Screen.	Vacuum did not reach the level required for the Plasma Stage. Load may be releasing gases from plastic-like materials. Press HELP for more instructions. If the cycle cancels again, call your ASP Service Representative.
CYCLE CANCELED LOW PRESSURE IN DIFFUSION PLEASE WAIT... 10 MIN.	Cycle Canceled Low Pressure In Diffusion Call ASP Technical Service	Atmospheric pressure has not been reached during diffusion. Unit fails to vent. Run an empty chamber cycle. If the cycle cancels again, call your ASP Service Representative.
CYCLE CANCELED LOW PRESSURE IN INJECTION PLEASE WAIT... 10 MIN	Cycle Canceled Low Pressure In Injection Refer To Help Screen	The peroxide pressure is too low due to a possible problem with the materials in the load. Press HELP for detailed instructions on how to resolve this problem. If you run an empty chamber cycle and the cycle cancels again, call your ASP Service Representative.
CYCLE CANCELED LOW RF POWER PLEASE WAIT... 10 MIN	Cycle Canceled Low RF Power In Vacuum. Refer To Help Screen or Cycle Canceled Low RF Power Refer To Help Screen or Cycle Canceled Low RF2 Power In Vacuum. Refer To Help Screen	Plasma power is too low. This may be caused by the load coming into contact with the electrode, the door or the chamber. Press HELP for information on how to resolve this problem. If the cycle cancels after an empty chamber cycle has been run, call your ASP Service Representative.

Displayed Message	Printed Message	Action
CYCLE CANCELED NO RF POWER PLEASE WAIT... 10 MIN.	Cycle Canceled No RF Power In Vacuum. Refer To Help Screen or Cycle Canceled No RF Power Refer To Help Screen or Cycle Canceled No RF2 Power In Vacuum. Refer To Help Screen	No RF or RF2 generator power. This may be caused by the load touching the electrode, the door, or the chamber. Press HELP for more information. If the cycle cancels after an empty chamber cycle has been run, call your ASP Service Representative.
CYCLE CANCELED OPERATOR CANCELLATION PLEASE WAIT...	Cycle Canceled Operator Cancellation Repackage Load Restart Sterilizer	The operator canceled the cycle. Press HELP for more information.
CYCLE CANCELED OVER PRESSURE IN INJECTION PLEASE WAIT... 10 MIN	Cycle Canceled Over Pressure In Injection Refer To Help Screen	Possible air leak in system or there is a problem with the load. Press HELP for more information. If you run an empty chamber cycle and the cycle cancels, call your ASP Service Representative.
CYCLE CANCELED POWER INTERRUPTED PLEASE WAIT...10 MIN	Cycle Canceled Power Interrupted	Power was interrupted during a critical phase of the cycle. Call your ASP Service Representative.
CYCLE CANCELED PRESSURE OUT OF RANGE PLEASE WAIT... 10 MIN	Cycle Canceled Pressure Out Of Range In Plasma Call ASP Technical Service or Cycle Canceled Pressure Out Of Range In Vacuum Refer To Help Screen	The pressure in the chamber did not stabilize in the range necessary to create a vacuum or a plasma state. There may be wet items in the load. WARNING! WEAR LATEX, PVC (VINYL) OR NITRILE GLOVES WHEN REMOVING THE LOAD FROM THE CHAMBER AND WHILE CHECKING ITEMS FOR MOISTURE. Press HELP for more information, or, if you have

6 Troubleshooting

Displayed Message	Printed Message	Action
		run an empty chamber cycle and the cycle cancelled, call your ASP Service Representative.
CYCLE CANCELED RF INTERRUPTED PLEASE WAIT... 10 MIN.	Cycle Canceled RF Interrupted In Vacuum Refer To Help Screen or Cycle Canceled RF Interrupted Refer To Help Screen	RF generator reflected power is too high. RF delivered power is too low. Something may be touching the electrode, door or the chamber walls. Press HELP for more information or if you have run an empty chamber cycle and the cycle cancelled, call your ASP Service Representative.
CYCLE CANCELED TEMPERATURE BELOW THRESHOLD PLEASE WAIT... 10 MIN.	Temperature Below Threshold Call ASP Technical Service	Call your ASP Service Representative.
CYCLE CANCELED TEMPERATURE OVER THRESHOLD PLEASE WAIT... 10 MIN.	Cycle Canceled Temperature Over Threshold Call ASP Technical Service	Call your ASP Service Representative.
CYCLE CANCELED VACUUM INSUFFICIENT PLEASE WAIT...	Cycle Canceled Vacuum Insufficient Refer To Help Screen	The items in the load may have contained too much moisture before they were placed in the sterilizer. WARNING! WEAR LATEX, PVC (VINYL) OR NITRILE GLOVES WHEN REMOVING THE LOAD FROM THE CHAMBER AND WHILE CHECKING ITEMS FOR MOISTURE. Press HELP for more information, or if you have run an empty chamber cycle and the cycle cancelled, call your ASP Service Representative.

Displayed Message	Printed Message	Action
CYCLE CANCELED VACUUM NOT LOW ENOUGH PLEASE WAIT... 10 MIN.	Cycle Canceled Vacuum Not Low Enough For Injection Refer To Help Screen	The items in the load may have contained too much moisture before they were placed in the sterilizer. WARNING! WEAR LATEX, PVC (VINYL) OR NITRILE GLOVES WHEN REMOVING THE LOAD FROM THE CHAMBER AND WHILE CHECKING ITEMS FOR MOISTURE. Press HELP for more information , or if you have run an empty chamber cycle and the cycle cancelled, call your ASP Service Representative.
CYCLE CANCELED VACUUM SYSTEM INTERRUPTED PLEASE WAIT...	Cycle Canceled Vacuum System Interrupted Call ASP Technical Service	Call your ASP Service Representative.
CYCLE CANCELED VAPORIZER BELOW THRESHOLD PLEASE WAIT... 10 MIN.	Cycle Canceled Vaporizer Below Threshold Call ASP Technical Service	Call your ASP Service Representative.
INCORRECT CASSETTE TYPE PLEASE REMOVE CASSETTE	No printout.	The cassette you are using is not recognized by the system. Insert a STERRAD® 50 Cassette.
INSERT NEW CASSETTE	No printout.	You have tried to start a cycle without inserting a cassette. Insert a new cassette and press START.
INSERT NEW CASSETTE CALL ASP TECHNICAL SERVICE	No printout.	Insert a new cassette. The specified planned maintenance is due now. Call your ASP Service Representative immediately.
INSERT NEW CASSETTE MAINTENANCE DUE (XXX)	No printout or Maintenance Due (XXX): NN	Insert a new cassette. The specified planned maintenance is due. Call your ASP Service Representative to schedule service.

6 Troubleshooting

Displayed Message	Printed Message	Action
PLEASE CLOSE DOOR	No printout.	Close and latch the door.
PLEASE REMOVE CASSETTE	No printout.	Remove the cassette. If the message persists, try a new cassette.
POSITIONING CASSETTE	No printout.	The cassette is being positioned.
PROCESS COMPLETE OPEN DOOR TO REMOVE LOAD	Maintenance Due (XXX): NN	The specified planned maintenance is due. Call your ASP Service Representative to schedule service.
PROCESS COMPLETE OPEN DOOR TO REMOVE LOAD	XXX PM Interval Past Due Call ASP Technical Service (NN)	The specified planned maintenance time is due now. Call your ASP Service Representative.
PROCESS COMPLETE OPEN DOOR TO REMOVE LOAD	STERRAD® 50 STERILIZER [Printout contains all process parameters.] PROCESS COMPLETE Validated By: _____ Biological Indicator: _____ CASS. LOT # XXXX EXP. DATE: MM/YYYY NUMBER OF CYCLES AVAILABLE = X REMOVE CASSETTE	The cycle is complete with no error. The door may be opened and the load removed and used or stored according to your facility's procedures.
READY TO USE	No printout.	The system is ready for a new cycle.
READY TO USE CALL ASP TECHNICAL SERVICE	No printout.	The specified planned maintenance is due now. Call your ASP Service Representative immediately.
READY TO USE MAINTENANCE DUE (XXX)	No printout.	The specified planned maintenance is due. Call your ASP Service Representative to schedule service.

Displayed Message	Printed Message	Action
SOFTWARE FAULT PLEASE WAIT...	Software Fault Call ASP Technical Service	Call your ASP Service Representative.
SYSTEM CANCEL PLEASE WAIT... 10 MIN.	System Cancel Call ASP Technical Service	Call your ASP Service Representative.
SYSTEM DATA UNREADABLE	No printout.	Call your ASP Service Representative.
TEMPERATURE HAS NOT RISEN CALL ASP TECHNICAL SERVICE	Temperature Has Not Risen Call ASP Technical Service	Call your ASP Service Representative.
TEMPERATURE OVER THRESHOLD CALL ASP TECHNICAL SERVICE	Temperature Over Threshold Call ASP Technical Service	Call your ASP Service Representative.
TEMPERATURE SENSOR BELOW THRESHOLD CALL ASP TECHNICAL SERVICE	Temperature Sensor Below Threshold Call ASP Technical Service	Call your ASP Service Representative.
UNABLE TO POSITION CASSETTE	No printout.	The cassette could not be positioned properly. If the cassette has ejected, remove the cassette and insert a new one. If the cassette did not eject, press the EJECT CASSETTE button. If the cassette ejects successfully, insert a new one. If this does not resolve the problem, call your ASP Service Representative.
VENT TIME-OUT CALL ASP TECHNICAL SERVICE	Vent Time-Out Call ASP Technical Service	Call your ASP Service Representative.
VERIFYING CASSETTE PLEASE WAIT...	No printout.	The system is trying to read the barcode; it tries twice. No action is required.
WARMING UP PLEASE WAIT	No printout.	The chamber is not yet at operating temperature. No action required, however if the message has not changed within 1 hour, call your ASP Service Representative..

6 Troubleshooting



Appendix A.

In this appendix . . .

- *sterilizer specifications*

Specifications

Space Requirements	
Size including cart	1 meter x 1 meter (3 feet x 3 feet)
Operation	
Electrical	120 VAC, 60 Hz, 15 Amps 220-240 VAC, 50/60 Hz, 10 Amps 100 VAC, 50/60 Hz, 20 Amps
Ambient Temperature	+15°C to +40°C (58-103° F)
Relative Humidity	10% to 80%, non-condensing
Pollution Degree	2
Overvoltage Category	II
Equipment Rating	
High Voltage	220-240 VAC, 50/60 Hz, 10 Amps
Low Voltage	120 VAC, 60 Hz, 15 Amps 100 VAC, 50/60 Hz, 20 Amps
Electrical requirements	
The STERRAD® 50 Sterilizer should only be plugged into outlets that have been approved by a qualified technician. For further requirements, refer to the label on the back panel of the sterilizer or call your ASP Service Representative. Only a qualified technician can determine when the STERRAD 50 Sterilizer can be safely moved to a new power source.	
Transport and Storage	
Ambient Temperature	+5°C to +60°C (40-139° F)
Relative Humidity	10% to 85%
Maximum Altitude	2,000 meters (6,561.6 feet)

Protection	
Protection Class	Class 1
Protection Type	Type B
Protection Against Ingress of Water	Ordinary (IPXO)
Mode of Operation	Continuous
Explanation of Warning Symbols	
IEC 378-03-0 	Attention, consult accompanying documents
IEC 878-03-0 	Dangerous voltage
Serviceable Assemblies	
Circuit Diagrams	Contact ASP Customer Support*
Component Part Lists	Contact ASP Customer Support*
Descriptions	Contact ASP Customer Support*
Calibration Instructions	Contact ASP Customer Support*

* ASP provides servicing information only to appropriately qualified personnel and only for assemblies that ASP feels are serviceable by non-ASP personnel. This information is available on request and may consist of circuit diagrams, component part lists, descriptions, and calibration instructions.

Appendix B.

In this appendix . . .

- *service and commercial warranties*

B

Service and Commercial Warrantees

Service and Commercial Warrantees

Advanced Sterilization Products Service Warranty

Service repairs are warranted to be free from defects in materials and workmanship for a period of 90 days after the date of repair when serviced by an ASP Representative or authorized dealer.

This warranty is null and void if service is performed by persons who are not authorized to do so by Advanced Sterilization Products. If, after examination by an ASP Service Representative, the previously repaired portion of the unit is found to be defective within the period specified above, and ASP is satisfied that the failure was due to defective materials and/or workmanship, ASP will, at its option, repair or replace the defective parts without charge. This warranty is not valid for repair or replacement for defects due to external factors including, but not limited to, defective electrical installation or electrical/atmospheric disturbances. ASP reserves the right to make the necessary repair in its own factory, at any authorized repair station, or at the facilities of the purchaser of the instrument. Replacement items can be either new or remanufactured. Defective parts replaced under warranty shall become the property of ASP.

THE EXPRESS WARRANTY ABOVE IS THE SOLE WARRANTY OBLIGATION OF ADVANCED STERILIZATION PRODUCTS, AND THE REMEDY PROVIDED ABOVE IS IN LIEU OF ANY AND ALL OTHER REMEDIES. THERE ARE NO OTHER AGREEMENTS, GUARANTEES OR WARRANTIES -- ORAL OR WRITTEN -- EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. ADVANCED STERILIZATION PRODUCTS SHALL HAVE NO LIABILITY WHATSOEVER FOR ANY IMPROPER USE OR UNAUTHORIZED SERVICE OR REPAIR.

Advanced Sterilization Products Commercial Warranty

The STERRAD® Sterilizer and reusable accessories supplied by Advanced Sterilization Products (ASP) are warranted to be free from defects in materials and workmanship for a period of one [1] year from the date of installation, when properly installed, maintained and used for their intended purpose. This warranty applies only to the original purchaser of the equipment and only if the equipment is used in the country to which it was originally shipped by Advanced Sterilization Products.

This warranty is null and void if service is attempted or performed by persons who are not authorized to do so by Advanced Sterilization Products. If, after examination by an ASP Service Representative, any portion of the unit is found to be defective within the period specified above, and ASP is satisfied that the failure was due to defective materials and/or workmanship, ASP will, at its option, repair or replace the defective parts without charge. This warranty is not valid for repair or replacement for defects due to external factors including, but not limited to, defective electrical installation or electrical/atmospheric disturbances. ASP reserves the right to make the necessary repair/replacement in its own factory, at any authorized repair station, or at the facilities of the purchaser of the instrument. Replacement items can be either new or remanufactured. Defective parts replaced under warranty shall become the property of ASP.

ACCEPTED
with COMMENTS
EPA Letter Dated:

FEB 1 2008

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

71871-3

